



Global Malaria Programme

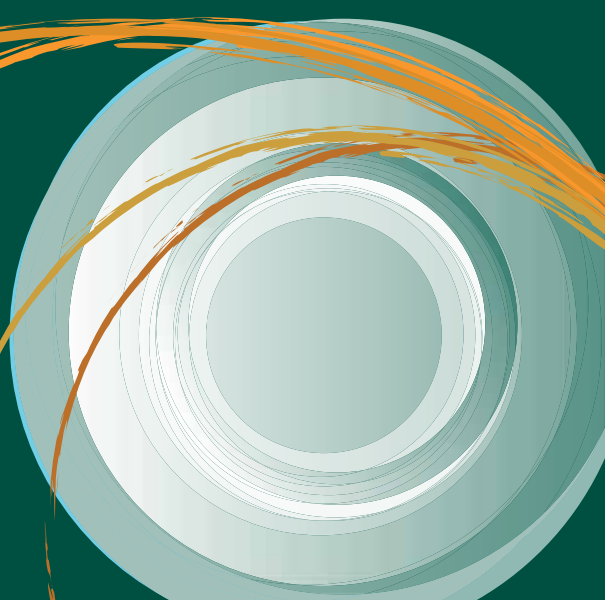
MALARIA CASE MANAGEMENT

OPERATIONS MANUAL

MALARIA CASE MANAGEMENT – OPERATIONS MANUAL



World Health
Organization



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Abbreviations used

AIDS	acquired immunodeficiency syndrome
ACT	artemisinin-based combination therapy
AM	artemether
AT	artemotil
AL	artemether-lumefantrine
AS	artesunate
AQ	amodiaquine
CQ	chloroquine
DIT	district investigation team
HIV	human immunodeficiency virus
HRP-II	histidine-rich protein II
ITN	insecticide-treated net
IPT	intermittent preventive treatment
IPT1	first dose of intermittent preventive treatment
IPT2	second dose of intermittent preventive treatment
M	mefloquine
QNN	quinine
RDT	rapid diagnostic test
SP	sulfadoxine-pyrimethamine
WHO	World Health Organization

1. Introduction

1.1 Background

Globally, 300–500 million episodes of malarial illness occur each year, resulting in over one million deaths, most of which are among children under five years of age. The greatest burden of malarial disease and death lies with the poor, who also have the least access to interventions against malaria. Malaria control requires an integrated approach, comprising prevention (including vector control) and treatment with effective antimalarial agents. Lack of information, education and access to early diagnosis and prompt, effective treatment has impeded the success of the global malaria programme in reducing severe morbidity and mortality from the disease.

Strategies for malaria case management should be considered an integral part of malaria control programmes. They must be based on sound epidemiology in the area in question, taking into consideration the population at greatest risk, including young children, pregnant women, residents of certain geographical areas and occupational risk groups, as well as the seasonality of malaria. Knowledge about the local pattern of resistance of parasites to antimalarial drugs is also essential in planning case management.

Most symptomatic malaria is treated in communities, in peripheral primary health facilities and in informal health structures. Therefore, an effective case management strategy requires that appropriate measures be taken to ensure access to appropriate, effective treatment at each level of health care, including the private sector and communities, as close to the patients as possible. It is important to ensure use of standard treatment guidelines, the availability and delivery of effective antimalarial medicines, health education and training and monitoring of clinical staff at all levels of health care delivery.

The affordable, previously widely available antimalarial drugs chloroquine and sulfadoxine-pyrimethamine, which were the mainstay of treatment, are now ineffective in most areas endemic for *Plasmodium falciparum* malaria. Increased resistance to these monotherapies has contributed to an increase in mortality from malaria in recent years. Artemisinin-based combination treatments are generally considered to be the best current treatment for uncomplicated falciparum malaria, and their accessibility to populations at risk and rational use must be ensured. The current malaria treatment guidelines formulated by the World Health Organization (WHO) recommend parasite-based diagnosis for older children and adults in all malarial settings and clinical diagnosis for children under five years of age in areas of high transmission.

Artemisinin-based combinations are recommended for treatment of uncomplicated falciparum malaria in all age groups, except during the first trimester of pregnancy, and parenteral quinine, artesunate or artemether are the recommended treatments for severe malaria.

1.2 Purpose and aims of the manual

The purpose of this manual is to advise those responsible for national malaria control programmes on the best ways of ensuring access to early diagnosis and appropriate, effective case management based on sound practice and WHO's experience in the use of artemisinin-based combination treatment. The manual describes malaria programme management, planning and implementation and outlines the technical knowledge needed for case management. It is intended for adaptation and use in all malaria-endemic countries, irrespective of their epidemiological and socioeconomic specificities.

The aim of this manual is to help to ensure that malaria control programmes at national, provincial, district (used here to indicate the first subnational administrative level) and community levels are efficiently and effectively organized to allow early diagnosis and prompt, effective treatment. The manual provides basic information for the successful operation of malaria control programmes and defines the skills required in the following areas:

- programme structure, planning and management;
- assessment of the available institutional capacity and human resources and identification of ways to support effective case management;
- planning effective malaria case management and identifying technical and managerial elements that require revision or reorientation;
- logistical organization to ensure regular supplies of medicines, diagnostics and other consumables;
- conducting quality assurance;
- planning training, health education and communication for behaviour change;
- planning supervision, monitoring and evaluation and revising malaria management information systems;
- coordinating and integrating malaria control programmes with other public health programmes and the private sector.

1.3 Intended readership

The manual's intended readership is personnel responsible for planning, organizing and supervising malaria control, especially malaria case management, at provincial, regional or national level, in ministries of health or in projects supported by international and multilateral cooperation agencies or nongovernmental organizations.

The manual is intended for use in particular by multidisciplinary teams involved in managing national malaria control programmes, including programme managers, epidemiologists, programme supervisors, provincial and district medical officers, medical superintendents or hospital administrators, pharmacists, clinicians, nurses, laboratory technicians, parasitologists, statisticians, health educators, logistics officers and trainers.

Health project managers dealing with malaria at national, district and community levels, including those responsible for private health services, will also find this manual useful. It could also be used as a resource in medical, nursing, laboratory and public health schools for training in effective malaria case management.

2. Defining the clinical profile of malaria patients

One of the first activities in designing and planning health services for malaria is identifying the clinical profile of the malaria patients in the area. The clinical profile varies greatly from one region of the world to another, depending on the species of malarial parasite (e.g. *Plasmodium falciparum*, *Plasmodium vivax* and other species) and the epidemiology of malaria (e.g. high or low transmission, stable or unstable epidemic) (Fig. 1). The clinical profile of malaria (Fig. 2) is defined by:

- the age and population distribution of malaria, e.g. mainly in children and pregnant women or in all age groups;
- the severity of the disease, e.g. acute disease with high morbidity in non-immune persons or milder disease with low morbidity such as in partially

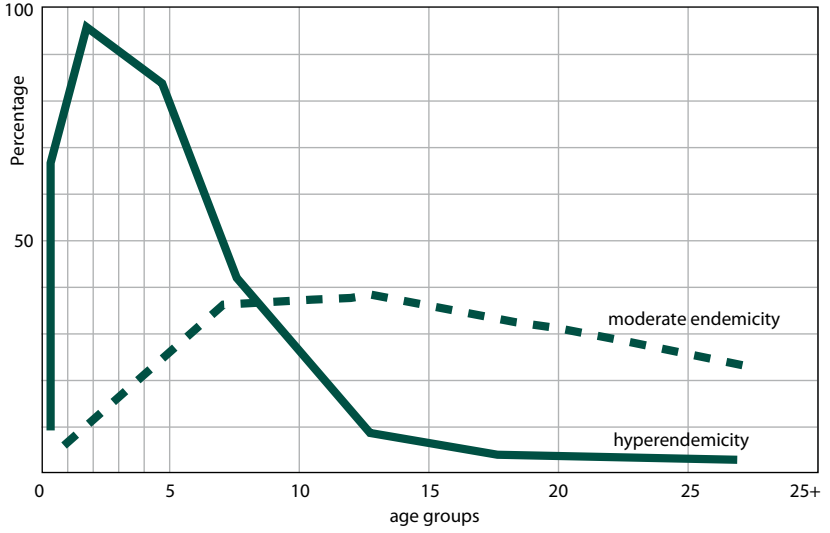


Figure 1 Schematic representation of the incidence rate of clinical malaria in areas of stable malaria and high transmission and in areas of unstable malaria and low to moderate transmission

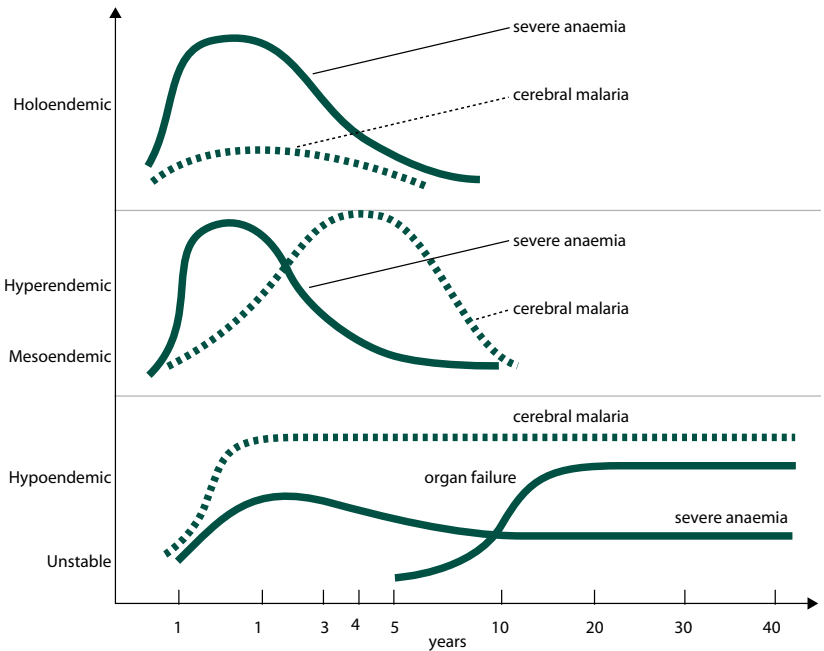


Figure 2 Schematic representation of the types of clinical presentation of malaria in relation to malaria epidemiology

immune persons; and whether it progresses rapidly to severe malaria and death; and

- the clinical type of disease, e.g. severe anaemia, cerebral malaria, single-organ or multiple-organ failure syndromes.

The clinical profile of malaria in an area determines the kind of health care services needed. For instance, if the disease occurs mainly in children, the system will focus on paediatric services. If the disease is acute, rapidly progressing and fatal, the health care services must be provided both at the level of the community (to ensure early treatment) and of tertiary institutions (for intensive care for severe disease). **Tables 1–3** show the implications for malaria case management according to the clinical profile of malaria in a particular area.

In areas of stable malaria and high malaria transmission (**Table 1**), such as tropical Africa and Papua New Guinea:

- most malaria cases are due to *P. falciparum* and are potentially lethal;
- the burden of malaria is predominantly in children;
- clinical care must be provided at all levels but especially at community level, with home management, and at tertiary institutions with good referral facilities for immediate transfer of patients with severe disease;
- pregnant women and their unborn infants are at high risk of morbidity, and provision should be made in maternal and child health services for prompt, effective treatment of malaria.

Table 1 Clinical profile of malaria and implications for case management in areas of stable malaria and high transmission

Age of patient	Clinical burden (incidence rate of disease)	Clinical picture	Notes on diagnosis and treatment
Infants	High	Fever, high parasitaemia, rapid progression of disease to severe malaria and death	<ul style="list-style-type: none"> – Treat on clinical suspicion – Early treatment in the community and referral very important – Demand for tertiary care services for severe malaria will be high
Children 2–5 years	Mainly after 4 months of age		
Children > 5 years	Low	Fever, moderate parasitaemia, semi-immune and therefore risk of severe disease not very high, except in pregnant women	<ul style="list-style-type: none"> – Seek parasitological confirmation of diagnosis where possible
Adolescents and adults			

In areas of unstable malaria and low to moderate malaria transmission (Table 2), such as much of tropical Asia, Latin America and Central Asia:

- both *P. vivax* and *P. falciparum* malaria are often prevalent;
- malaria is an important but not necessarily the predominant public health problem;
- diagnostic services are critically important to differentiate species and to distinguish malaria from other febrile illnesses;
- immunity to malaria is low in all age groups, and therefore the risks for disease and death from unrecognized malaria are high at almost all ages;
- malaria treatment services at primary health care level are important in order to prevent severe malaria and mortality.

In malaria epidemics, which can occur in areas of unstable malaria as well as in areas of stable malaria due to a high influx of non-immune or susceptible populations (Table 3):

- both *P. vivax* and *P. falciparum* malaria can be prevalent;
- as immunity to malaria is low in all age groups, the risks for disease and death are high at all ages;
- malaria case management can rapidly overwhelm both paediatric and adult clinical services within a short time;
- diagnostic services are critically important in order to confirm an epidemic but are not essential thereafter; disease management during the acute phase of the epidemic consists of mass treatment of febrile patients.

Table 2 Clinical profile of malaria and implications for case management in areas of unstable malaria and low to moderate transmission

Age of patient	Clinical burden (incidence rate of disease)	Clinical picture	Notes on diagnosis and treatment
Infants	Low	Fever, moderate to high parasitaemia, rapid progression of disease to severe malaria and death if treatment is delayed	<ul style="list-style-type: none"> – Early treatment and referral important at primary health care level – Parasitological confirmation of diagnosis recommended – Demands intensive care services for management of severe malaria
Children 2–5 years			
Children > 5 years	High		
Adolescents and adults			

Table 3 Clinical profile of malaria and implications for case management in malaria epidemics

Age of patient	Clinical burden (incidence rate of disease)	Clinical picture	Notes on diagnosis and treatment
Infants	High	Sudden and large increase in number of patients Fever, high parasitaemia, rapid progression of disease to severe malaria and death if treatment is delayed	<ul style="list-style-type: none"> – Early treatment and referral important at primary health care level – Parasitological confirmation of diagnosis is important, especially in the early stage of the epidemic – Demands intensive care services for management of severe malaria
Children 2–5 years			
Children > 5 years	High		
Adolescents and adults			

3. Structure and management of the malaria control programme

The main objective of malaria treatment is to cure infection and to prevent death from severe malaria. This is achieved by ensuring efficient, effective treatment as quickly as possible after the onset of symptoms – ideally, within 24 hours for falciparum malaria. Thus, the likelihood of severe malaria is reduced and few cases progress. Another important objective of treatment is to reduce the reservoir of people with malaria infection in order to reduce the chances of transmission of malaria parasites to others.

To support these objectives, specific national policies are required to guide malaria case management services and surveillance. Planning for effective service delivery should be based on the population at risk, the burden of disease, the quality of service and its accessibility. It is the responsibility of the national malaria control programme to define strategies, with clear short- and long-term objectives, and to set targets. In planning for efficient, effective case management, it is important to consider:

- **accessibility:** user-friendly diagnostic and treatment services as close to the patients' homes as possible;

- **availability:** continuous supplies of antimalarial medicines, diagnostics and other consumables;
- **quality of services:** competent, skilled providers, high-quality, effective medicines and reliable diagnostic services;
- **equity:** equal access to malaria services by disadvantaged populations at risk (e.g. children under five years of age, women, populations in remote areas, minority ethnic groups, and people living with HIV/AIDS);
- **affordability:** cost that is not a deterrent to treatment;
- **communication for behavioural change:** well-disseminated and well-understood information on malaria disease, health-seeking behaviour, prevention and treatment, to ensure the appropriate use of health services.

Integral to planning is an assessment of the existing capacity of the health system in the country to deliver the necessary services.

3.1 Assessment of service delivery

Malaria risk areas must be defined, and the number, type and level of public and private non-profit and for-profit health facilities, including their geographic and population coverage, must be assessed. The availability and level of diagnostic and treatment services in the facilities determine the case management strategy. Community malaria case management, or home management of malaria, might be needed to ensure treatment when access to health facilities is poor.

3.1.1 Delivery infrastructure

For effective planning, the capacity of the following to deliver malaria case management should be assessed:

- public health services (hospitals, health centres and primary level clinics), including the population served by each type of facility;
- non-profit health facilities, including their distribution and catchment populations (nongovernmental organizations and faith-based health facilities);
- private for-profit health providers (especially in urban and periurban areas);
- community health structures (community health workers, agents or volunteers involved in health service delivery).

Often, malaria is treated outside the public sector, mainly within the private sector, both formal and informal. A full evaluation of the role of the private sector in overall health services delivery, the types of providers, coverage, prac-

tices and quality will be required to establish its role and its capacity to increase the access of the population to high-quality malaria case management.

3.1.2 Human resources

One of the greatest limitations to ensuring access to early diagnosis and effective treatment is the lack of adequately trained, motivated human resources in public health, including programme managers, doctors, nurses, pharmacists, laboratory technicians, data managers and other skilled health providers. In planning a national, provincial or district case management strategy, a systematic assessment should be made of existing staffing patterns, including:

- number, skills and terms of reference of key public health staff required to manage a malaria programme at national, provincial and district levels;
- number and staffing levels of physicians, nurses and other medical or para-medical staff providing curative services and their population coverage;
- type, number, qualifications and distribution of laboratory professionals and technicians who perform microscopy for diagnosis of malaria;
- number, distribution and tasks of community health workers, agents or volunteers dealing with malaria at village or community level.

Human resource requirements and staffing models to ensure the quality of service delivery should be evaluated locally on the basis of the resources available.

The persons involved in malaria case management at country level are shown in the [figure 3](#).

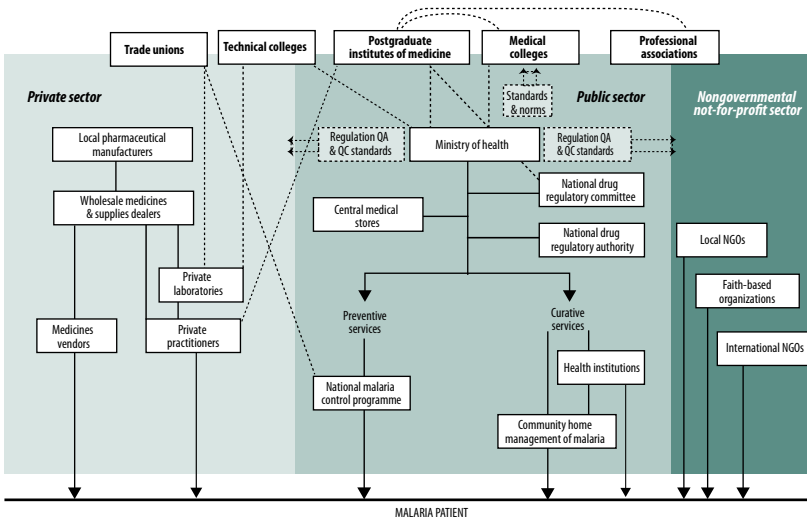


Figure 3 Malaria case management stakeholders in the national context

3.2 National malaria control programmes

3.2.1 Structure

The administrative structure for malaria control should be integrated into the organizational structure of health service delivery and the political administration of the country. The principles advocated by the WHO Global Malaria Programme for the programme management structure are a well-established national malaria control programme under the ministry of health, a provincial or district management structure and clear links with health institutions and communities. The management structures should be politically supported and have enough resources to provide high-quality services. Even when health services are integrated and decentralized, appropriate management structures are needed to support malaria control activities.

For effective programme management and implementation of malaria control at central level, a minimum number of competent staff is needed. The minimum staffing levels recommended by the WHO Global Malaria Programme should be sufficient to enable specific officers to be responsible for managing at least the eight key programme areas specified in the organizational chart shown in the [figure 4](#).

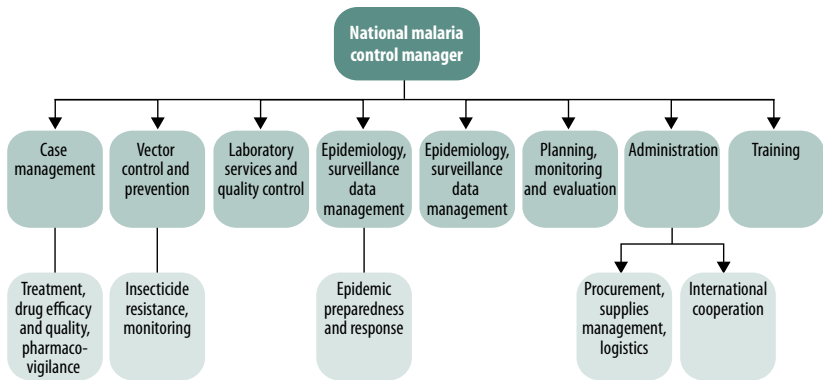


Figure 4 National malaria control programme structure

IEC = information, education and communication

3.2.2 Functions

It is the responsibility of the ministry of health through the national malaria control programme to design a malaria control strategy, to set objectives and targets and to ensure implementation of activities, including adequate funding.

Therefore, at national level, the main functions of a national malaria control programme are as follows:

- to formulate malaria control policies;
- to design and support a national malaria control strategy;
- to formulate national malaria control plans, including setting targets;
- to set standards and conduct quality assurance;
- to mobilize resources for implementation of activities and coordinate external funding;
- to build capacity and provide technical support;
- to supervise, monitor and evaluate malaria-related activities in the country;
- to conduct malaria surveillance (case reporting, drug safety, drug and insecticide resistance);
- to coordinate operational research on malaria.

3.2.3 Malaria case management policy

National malaria control programmes must define a clear malaria treatment policy based on surveillance of drug efficacy in the country. The policy should state which medicine(s) are to be used as first- and second-line treatment for uncomplicated malaria and for severe malaria and should provide clear guidance for case management in special groups (pregnant women, children aged under five and people living with HIV/AIDS). All countries in which *P. falciparum* malaria is endemic should adopt the use of oral artemisinin-based combination treatments for uncomplicated malaria and parenteral artemisinins or quinine for initial treatment of severe malaria. In countries where there is *P. vivax* malaria, chloroquine or amodiaquine followed by primaquine radical treatment cure are still effective.

Case management guidelines should be revised to concord with the agreed policies for diagnosis and treatment of malaria. The national treatment guidelines should be reflected in practice and communicated in a timely manner to the public and private sectors, including the general population. The treatment policy should also indicate which antimalarial agents are registered and marketed in the country. WHO currently encourages all countries in which artemisinin-based combination treatments are used to stop the marketing of artemisinin derivative monotherapy in order to reduce the spread of resistance to these medicines.

To ensure proper coordination, a medical officer must be appointed to oversee malaria case management within the national programme. The role of the case management officer is to facilitate the formulation, implementation, monitoring and evaluation of the treatment policy. In addition, officers should

be appointed to oversee drug efficacy studies, malaria laboratory services and pharmacovigilance for antimalarial drugs, in close cooperation with the national drug regulatory authority and the national pharmacovigilance centre.

A support team of professional staff is needed for case management activities at national and district levels. It is recommended that a working group composed of clinicians working in central and district hospitals, pharmacists, laboratory technicians and nurses be established, to provide a forum for discussion and decision-making on diagnosis and treatment of malaria. The working group would:

- periodically review and advise the national malaria control programme on malaria treatment policy;
- periodically review and update the national guidelines and training materials for malaria case management;
- ensure high-quality training of health workers and paramedical staff;
- supervise health workers and laboratory technicians in collaboration with national malaria control programme staff.

3.3 Malaria control at subnational level

Subnational structures responsible for planning and implementation of malaria prevention and control measures can be at the level of local government areas, districts, states, regions or municipalities. In most countries, malaria control activities are micro-planned and implemented at subnational level; this is therefore an important level at which to ensure service delivery. The malaria programme management structure and capacity should be well established, depending on the degree of decentralization of health services.

3.3.1 Structure

To ensure adequate microplanning, supervision, monitoring and evaluation of malaria control activities at subnational level, a focal point is needed. A position should be created by the national malaria control programme, or a focal person should be identified at subnational level, e.g. from the district health management team. In countries where the malaria control programme is integrated into peripheral health services, this person will have other tasks to perform in addition to malaria control. The district malaria officer or focal person will be responsible for malaria control in the district health management team and will liaise with other district health staff and partners to ensure effective case management.

3.3.2 Functions

The main function of the district health management team is to coordinate and plan all malaria control activities in the district. The key functions in malaria case management include:

- planning on the basis of the epidemiology, existing health service infrastructure and access by the population at risk;
- ensuring that all public health facilities provide general outpatient services catering for malaria patients;
- ensuring the availability and quality of malaria diagnostic services;
- ensuring the availability of effective antimalarial medicines;
- designating the facilities in the district that will provide inpatient care for patients with severe malaria, according to the level of personnel and facilities available;
- ensuring high-quality training of district health workers and paramedical staff in malaria case management;
- providing technical supervision to health workers and laboratory technicians in collaboration with the district hospital or health centre staff;
- supervising private providers to ensure high-quality malaria diagnosis and treatment according to national treatment guidelines;
- ensuring that appropriate messages and educational materials are available to both providers and the community.

Planning at district level should cover the entire population, taking into account access to services, because distance, geographical barriers, lack of transport and poverty can prevent access to treatment. A significant proportion of the population might not be able to reach health facilities owing to remoteness or extreme poverty. It is important to remember that, in high-transmission areas, the high case-load seen during peak transmission seasons will require additional medical supplies and will entail an increased workload for health personnel. The diagnostic services (especially microscopy) might be overwhelmed and the quality of the examinations not be assured in the absence of adequate planning.

A subnational or district supervisory team should be responsible for the overall coordination and supervision of malaria case management in the health institutions. This can be a great challenge in large subnational administrative areas, because of the diversity of services and the small number of personnel available to supervise all facilities.

3.4 Malaria control at health unit level

Primary health care facilities play a major role in malaria control and often provide the bulk of malaria case management services in a country, usually both clinical services and overall programme management for community activities in the catchment area. District hospitals and large health centres usually have clinical and diagnostic services for outpatients and inpatients, act as referral centres and give support to lower-level facilities.

3.4.1 Structure

The structure of health units in relation to the community is shown [figure 5](#).



Figure 5 Health unit structure in relation to the community

3.4.2 Functions

Health facilities involved in malaria programme planning and provision of services should have well-established roles. Most facilities provide integrated clinical and community outreach services. To ensure adequate planning and provision of malaria case management, all health facility staff should be oriented and trained in both managerial and clinical service delivery. The key functions of primary health care facilities, depending on the level of staffing, include:

- planning malaria control activities to ensure early access to appropriate diagnosis and treatment at health units and in the community;
- ensuring adequate provision and availability of antimalarial medicines, diagnostics and other supplies for health units and the community;
- ensuring a clear flow of patients in outpatient departments who present with fever or a history of fever or anaemia;

- ensuring that patients are clinically assessed, that malaria is diagnosed from a blood smear or rapid diagnostic test and that the patients are treated with an appropriate antimalarial drug;
- ensuring that patients with severe malaria are referred after initial treatment;
- ensuring that the relevant information is recorded in a malaria patient register, summarized monthly and analysed before reporting to the district;
- assisting in community mobilization and providing technical support to community health workers through training and supervision in malaria control.

Planning should be based on the population of the area served by the health unit, to ensure that the services are reasonably planned and accessible. The case-load should be supported by adequate supplies and resources to ensure that the quality of service delivered is good, thereby encouraging the population to make good use of the health facility.

3.5 Malaria control at community level

The structure at community level depends on the local situation. For effective malaria control, it is important to activate existing community structures. Access to early, effective treatment can be achieved only when the community is aware of the problem and knows how to deal with it.

3.5.1 Home management of malaria

Health service coverage in many malaria-endemic countries is generally low, and many children and adults with fever are treated at home or close to home. Most children die at home without access to the health system. The behaviour of populations in seeking care for fever varies, depending on factors such as geographical access, poverty, community perceptions and the availability of medicines. It is therefore important to assess whether home management of malaria could be used to improve access to early diagnosis and treatment.

Implementation of home management requires partners, awareness and support. Partnership is important at all levels and can include community groups, key departments of ministries of health, other government sectors, the private sector, informal health providers, nongovernmental organizations, the mass media and bilateral and global development agencies.

In order to implement home management of malaria, the following should be planned:

- sensitization of district health teams and communities about the strategy;

- selection of community-based health providers to be trained, the number depending on the area to be served, but preferably at least two persons in each selected household;
- training of community-based health providers by district and health facility staff with the involvement of local leaders;
- establishment of a system for regular distribution of medicines, diagnostics, information for behaviour change, job aides and logistical support (e.g. storage facilities, forms, timers);
- monitoring and supervision of community-based health providers and the whole programme through documentation, record-keeping, quality assurance, information analysis and feedback to all levels;
- evaluating the system to increase motivation and to support and mobilize community-based health providers.

3.5.2 *Delivery structure*

Various community-based health providers can deliver prompt, effective treatment through home management of malaria. The providers can be drawn from the public sector, including existing community health workers and persons involved in other health-related community programmes. Those in the private or informal sector include commercial medicine sellers (chemical companies or patent medicine vendors), retail shopkeepers, traditional healers and traditional birth attendants. They could be newly trained for the purpose (e.g. malaria health volunteers or agents). To achieve good access, different community-based health providers should be recruited, depending on the existing community structures, resources and community needs.

3.5.3 *Functions*

Communities have a pivotal role in advocating and supporting malaria control activities and can improve trust and support for those activities. The main roles of communities are as follows:

- to select community-based distributors and distribution points;
- to participate in the collection and delivery of medicines from the nearest distribution point;
- to mobilize resources and support community health workers.

Community-based health providers should be selected through a locally appropriate process, with full community involvement. They should be reliable persons, preferably mothers or other caregivers, and the community should decide on the number required per area. The roles of community-based health providers are as follows:

- to assess and provide treatment to patients with fever or malaria;
- to tell mothers (caregivers) how to treat and prevent malaria at home, by ensuring that people sleep under a bednet;
- to explain the danger signs to mothers (caregivers);
- to refer children with danger signs to health facilities and explain the need to the caregivers;
- to follow up treated children to ensure that they comply with treatment and advice;
- to ensure good storage of drugs at community level;
- to record details of patients treated, drugs given, outcome of treatment and any adverse drug reactions.

For successful community implementation of the home management of malaria approach, health facilities and personnel must be equipped to provide training, support and supervision to community resource persons and to establish a referral service in the community. Health workers should be sensitized to home management of malaria, to ensure that their role in the strategy is well understood, so that they can support it and promote its adoption and implementation.

4. Technical aspects of malaria case management

The first symptoms of malaria are nonspecific and are similar to the symptoms of a minor systemic viral illness. They comprise headache, lassitude, fatigue, abdominal discomfort and muscle and joint ache, followed by fever, chills, sweating, anorexia, vomiting and worsening malaise. Infection with *P. vivax* and *P. ovale*, especially, can be associated with well-defined malarial paroxysms, in which fever spikes, chills and rigor occur at regular intervals.

If treatment is delayed or if ineffective antimalarial medicines are given to a patient with falciparum malaria, the disease may progress to severe disease within a few hours. This usually manifests as one or more of the following: coma (cerebral malaria), metabolic acidosis, severe anaemia, and hypoglycaemia and, in adults, acute renal failure or acute pulmonary oedema.

It is therefore important to diagnose or recognize malaria and to treat cases promptly and effectively, bearing in mind the essential components of malaria case management, which are disease recognition or prompt diagnosis, clinical and parasitological diagnosis, treatment with effective drugs, referral if necessary, counselling and follow-up.

Usually, health facilities are classified into three levels, with separate roles in malaria case management. At community level (home management), the roles are recognition and treatment of uncomplicated cases and recognition and referral of severe disease. Health facilities undertake diagnosis and treatment of malaria cases. Peripheral health facilities manage uncomplicated malaria and diagnosis and referral of severe cases after pre-referral treatment, while health centres and hospitals manage severe cases.

4.1 Diagnosis of malaria

Prompt, accurate diagnosis of malaria is part of effective disease management. High sensitivity in diagnosis is important in all settings, particularly for the most vulnerable groups, such as young children, in which the disease can rapidly be fatal. High specificity can reduce unnecessary treatment with anti-malarial medicines and improve differential diagnosis of febrile illness.

A diagnosis of malaria is based on clinical criteria (clinical suspicion) and detection of parasites in blood (parasitological or confirmatory diagnosis).

4.1.1 Clinical diagnosis

Clinical suspicion alone has little specificity, as the signs and symptoms of malaria are nonspecific. Malaria is suspected clinically mainly on the basis of fever or a history of fever. The following WHO recommendations are still considered valid for clinical diagnosis:

- *In settings where the risk of malaria is low*, clinical diagnosis of uncomplicated malaria should be based on the degree of exposure to malaria and a history of fever or fever in the previous three days with no features of other severe diseases.
- *In settings where the risk of malaria is high*, clinical diagnosis should be based on fever or a history of fever in the previous 24 hours and/or the presence of anaemia, for which pallor of the palms appears to be the most reliable sign in young children.

In all settings, clinical suspicion of malaria should be confirmed with a parasitological diagnosis. However, in settings where parasitological diagnosis is

not possible, the decision to provide antimalarial treatment must be based on the prior probability of the illness being malaria.

4.1.2 Parasitological diagnosis

Parasitological diagnosis has the following advantages:

- improved care of parasite-positive patients because of greater certainty that they have malaria;
- identification of parasite species;
- identification of parasite-negative patients, in whom another diagnosis must be sought;
- avoidance of unnecessary use of antimalarial medicines in parasite-negative patients, thereby reducing side-effects, drug interactions, selection pressure for drug resistance and savings, especially in view of the high cost of artemisinin-based combination treatments;
- confirmation of treatment failures.

The two methods commonly used for parasitological diagnosis are light microscopy and rapid diagnostic tests for detecting parasite antigens. Light microscopy has the advantage of low cost in situations of high case-load and high sensitivity and specificity when used by well-trained staff. Rapid diagnostic tests are generally more expensive, but the prices of some have decreased recently so that use is cost-effective in some settings. An operational constraint, however, is that their sensitivity and specificity are vulnerable to high temperatures and humidity.

The results of parasitological diagnosis should be available within less than two hours of presentation of the patient. If this is not possible, the patient must be treated on the basis of a clinical diagnosis. In all cases, if there is a strong clinical suspicion, the case should be treated as malaria.

WHO recommends parasitological confirmation (microscopy or rapid diagnostic test) before treatment for all suspected malaria cases. Antimalarial treatment on the basis of clinical suspicion should only be given in situations where parasitological diagnosis is not available, specially in vulnerable populations (children under five years of age and severe malaria).

The choice of using rapid diagnostic tests or microscopy depends on local circumstances, including the skills available, the use of microscopy for other diseases present in the area and the case-load. Light microscopy remains the gold standard for diagnosis, and rapid diagnostic tests should be used where microscopy is not available. When the case-load of patients with fever is high, microscopy is likely to be less expensive than rapid diagnostic tests. Microscopy can be used to identify species, quantify parasites and identify other causes of

fever. In situations where most malaria patients are treated outside the health services and in remote areas where good quality microscopy cannot be supported, rapid diagnostic tests might be useful.

The national malaria control programme should clearly define the diagnosis policy in each area. Further guidance on diagnosis policy is available at <http://www.who.int/malaria/diagnosisandtreatment.html>, which provides references to publications that also give more details of WHO recommendations on the choice of rapid diagnostic tests.

In areas where two or more species of malaria parasite are common, only a parasitological method will permit species diagnosis. In areas where only falciparum malaria occurs, or where *P. vivax*, *P. malariae* or *P. ovale* occur almost always as a co-infection with *P. falciparum*, rapid diagnostic tests that detect only *P. falciparum* are generally preferable on the grounds of lower cost. Where falciparum and non-falciparum infections occur commonly as single-species infections, combination tests to detect all species and to distinguish *P. falciparum* from non-falciparum infections are indicated. Where there is no falciparum malaria, rapid diagnostic tests to detect non-falciparum species alone are appropriate (*P. vivax*-specific or specific for malaria caused by all species).

4.2 Treatment of uncomplicated malaria

The primary objective in treating uncomplicated malaria is to achieve a clinical and parasitological cure and to eradicate parasites from the body. The secondary objective is to prevent the emergence and spread of resistance to antimalarial medicines. Another important objective of treatment is to reduce the parasite reservoir from which other persons will become infected, thus reducing transmission.

In the management of severe malaria, the primary objective of antimalarial treatment is to prevent death. Hence, the prevention of recrudescence and avoidance of minor adverse effects are secondary aims.

4.2.1 Uncomplicated *P. falciparum* malaria

In order to provide the best treatment available (to improve treatment outcome) and to counter the threat of resistance of *P. falciparum* to monotherapies, combinations of antimalarial medicines are now recommended by WHO for the treatment of falciparum malaria, including women in the second and third trimesters of pregnancy. Combination therapy is defined as the simultaneous use of two or more blood schizontocidal drugs with independent modes

of action to improve therapeutic efficacy and also to delay the development of resistance to the individual components of the combination.

The artemisinin compounds are active against all four species of malaria parasites that infect humans and are generally well tolerated. These drugs also have the advantage, from a public health perspective, of reducing gametocyte carriage and thus the transmissibility of malaria. With high treatment coverage, this contributes to malaria control in areas of low endemicity. The artemisinin-based combination treatments currently recommended are (in alphabetical order) artemether-lumefantrine, artesunate plus amodiaquine, artesunate plus mefloquine, and artesunate plus sulfadoxine-pyrimethamine. The *Malaria Treatment Guidelines* are currently being updated (2009), and another ACT – dihydroartemisinin-piperaquine – is being reviewed for inclusion as an option for treatment of uncomplicated malaria (the Guidelines update will be posted on the WHO malaria web site as soon as it is available and please, check for it at: <http://who.int/malaria>).

▪ Artemether-lumefantrine

Artemether-lumefantrine is available as fixed-dose combination containing 20 mg of artemether and 120 mg of lumefantrine in each tablet. The recommended treatment is a 6-dose regimen over a 3-day period. The dosing is based on the number of tablets per dose given twice a day for 3 days, according to pre-defined weight bands (5–14 kg: 1 tablet; 15–24 kg: 2 tablets; 25–34 kg: 3 tablets and over 34 kg: 4 tablets).

▪ Artesunate plus amodiaquine

This is currently available as co-formulated tablets in three strengths (25/67.5, 50/135 and 100/270 mg of artesunate and amodiaquine respectively in each tablet). The recommended treatment is a 3-dose regimen over a 3-day period. The target dose is 4 mg/kg of body weight of artesunate and 10 mg/kg of body weight of amodiaquine given as a single daily dose for 3 days. The current available product is dosed-based on the number of tablets following pre-defined weight bands. Co-packaged blister packs containing 50 mg artesunate and 153 mg base-amodiaquine are also available.

▪ Artesunate plus sulfadoxine-pyrimethamine

Artesunate plus sulfadoxine-pyrimethamine is currently available as separate, scored tablets containing 50 mg of artesunate and tablets containing 500 mg of sulfadoxine and 25 mg of pyrimethamine. (A similar preparation with tablets containing 500 mg of sulfalene and 25 mg of pyrimethamine is considered to be equivalent to sulfadoxine-pyrimethamine.) The total recommended treatment is 4 mg/kg of body weight of artesunate given once a day for 3 days and a single administration of sulfadoxine-pyrimethamine 1.25/25 mg/kg of body weight on day 1.

■ Artesunate plus mefloquine

Artesunate plus mefloquine is currently available as fixed-dose formulations with 25/55 mg and 100/200 mg tablets of artesunate and mefloquine, respectively. Blister packs with separate, scored tablets containing 50 mg of artesunate and 250 mg of mefloquine base are also available. The total recommended treatment is 4 mg/kg of body weight of artesunate given once a day for 3 days and 25 mg/kg of body weight of mefloquine base usually split over 2 or 3 days.

4.2.2 Treatment approaches

Counselling is encouraged, during which patients or caregivers are told of the importance of taking a full treatment course, told when to return for follow-up and what to do if they become sicker. Another important approach is to give the first dose of treatment at the health facility, which might require reorganization of patient flow.

Partial treatment should not be given, even when patients are considered to be semi-immune or the diagnosis is uncertain. A full course of effective treatment should always be given once a decision to give antimalarial treatment has been reached.

The artemisinin derivatives (oral formulations) and other components of artemisinin-based combination treatments should not be available as monotherapies, and efforts should be made to limit their availability, unless they serve a specific need (e.g. sulfadoxine-pyrimethamine for intermittent preventive treatment, chloroquine for *P. vivax* malaria).

4.2.3 Uncomplicated *P. vivax*, *P. ovale* and *P. malariae* malaria

Chloroquine or amodiaquine as monotherapy with primaquine for treatment of *P. vivax* malaria are still effective. Where artemisinin-based combination treatment has been adopted as first-line treatment for *P. falciparum* malaria, it can also be used against *P. vivax* malaria, followed by primaquine for radical cure. The only exception is artesunate plus sulfadoxine-pyrimethamine, which is not effective against *P. vivax* in many places. The recommended treatment for uncomplicated vivax malaria is as follows:

- Chloroquine 25 mg base/kg of body weight divided over 3 days, combined with primaquine 0.25 mg base/kg of body weight, taken with food once daily for 14 days is the treatment of choice for chloroquine-sensitive infections. In Oceania and South-East Asia, the dose of primaquine should be 0.5 mg/kg of body weight.
- ACTs combined with primaquine should be given for chloroquine-resistant vivax malaria.

- In moderate glucose 6-phosphate dehydrogenase deficiency, primaquine 0.75 mg base/kg of body weight should be given once a week for 8 weeks. In severe glucose 6-phosphate dehydrogenase deficiency, primaquine should not be given.

The resistance of *P. ovale* and *P. malariae* to antimalarials is not well characterized, and infections caused by these two species are considered to be generally sensitive to chloroquine. The recommended treatment for the relapsing malaria caused by *P. ovale* is the same as that given to achieve radical cure in vivax malaria, i.e. chloroquine and primaquine. *P. malariae* should be treated with the standard regimen of chloroquine used for vivax malaria, but it does not require radical cure with primaquine as no hypnozoites are formed in infections with this species.

P. ovale occurs mainly in areas of stable malaria and high transmission, where the risk of re-infection is high. In such settings, primaquine treatment is not indicated.

Rare cases of simian malaria (*P. knowlesi*) have been detected in humans. They should be treated with chloroquine.

4.3 Management of severe malaria

In a patient with *P. falciparum* asexual parasitaemia and no other obvious cause of symptoms, the presence of one or more clinical or laboratory features classifies the patient as suffering from severe malaria.¹ The clinical manifestations are as follows:

- prostration
- impaired consciousness
- respiratory distress (acidotic breathing)
- multiple convulsions
- circulatory collapse
- pulmonary oedema (radiological)
- abnormal bleeding
- jaundice
- haemoglobinuria.

1. Full definitions and prognostic factors are described in World Health Organization. Severe falciparum malaria. *Transactions of the Royal Society of Tropical Medicine and Hygiene*, 2000, 94(Suppl. 1):S1–S90, and World Health Organization. Management of severe malaria: a practical handbook, 2nd ed. Geneva, 2000.

Laboratory tests should therefore be carried out for:

- severe anaemia
- hypoglycaemia
- acidosis
- renal impairment
- hyperlactataemia
- hyperparasitaemia.

The management of severe malaria comprises four main areas: clinical assessment of the patient, specific treatment, adjunctive therapy and supportive care.

A national malaria control programme should define clear criteria for qualifying a health facility to manage severe cases, including continuity of care (24-hour working), trained staff and minimum equipment. Cases of severe anaemia should be treated only in health facilities with transfusion services.

4.3.1 *Specific treatment*

Severe malaria is a medical emergency. After rapid clinical assessment and confirmation of the diagnosis, full doses of parenteral antimalarial treatment should be started without delay with whichever effective antimalarial is first available. Two classes of drug are currently available for this purpose: cinchona alkaloids (quinine and quinidine) and artemisinin derivatives (artesunate, artemether and artemotil). Although there are a few areas in which chloroquine is still effective, parenteral chloroquine is no longer recommended for the treatment of severe malaria because of widespread resistance. Intramuscular sulfadoxine-pyrimethamine is also not recommended.

In low-transmission areas and outside malaria-endemic areas, artesunate at 2.4 mg/kg of body weight intravenously or intramuscularly on admission, then at 12 hours and 24 hours, then once a day is recommended.

For children in high-transmission areas, either artesunate at 2.4 mg/kg of body weight intravenously or intramuscularly on admission, then at 12 hours and 24 hours, then once a day; or artemether at 3.2 mg/kg of body weight intramuscularly on admission, then 1.6 mg/kg of body weight per day should be given. There is insufficient evidence to prefer one of these medicines rather than another.

Quinine salt can be given at 20 mg/kg of body weight on admission (intravenous infusion or divided intramuscular injection), then 10 mg/kg of body weight every 8 hours; the infusion rate should not exceed 5 mg/kg of body weight per hour.

After initial parenteral treatment and once the patient can tolerate oral therapy, treatment should be continued and completed with an effective oral antimalarial, comprising a full course of combination therapy with an effective artemisinin-based combination treatment or quinine plus clindamycin or doxycycline. Doxycycline and tetracyclines are contraindicated for children less than 8 years of age.

4.3.2 Pre-referral treatment options

The risk for death from severe malaria is greatest during the first 24 hours. Patients should be treated with the first dose of one of the recommended treatments, by the parenteral route if possible or intrarectally, before referral, unless the referral time is very short. The treatment could be intramuscular artemether, artesunate or quinine or a rectal formulation of artemisinin or artesunate. If, however, referral is impossible, parenteral or rectal treatment should be continued until the patient can tolerate oral medication, at which time a full course of the recommended artemisinin-based combination treatment for uncomplicated malaria in the locality can be administered.

Artesunate suppositories² are given at a dose of 10 mg/kg of body weight daily. Artesunate suppository are currently available as a 50 mg or 200 mg formulations. The appropriate single dose of artesunate given by suppository should be administered rectally as soon as a presumptive diagnosis of severe malaria is made. In the event that the suppository is expelled from the rectum within 30 minutes of insertion, a second suppository should be inserted and, especially in young children, the buttocks should be held together for 10 minutes to ensure retention of the dose. This dose should be given once and followed as soon as possible by definitive therapy for malaria.

The treatment with intramuscular artemether, artesunate or quinine should be given according to the recommended dosage for each of these three medicines.

4.3.3 Adjunctive treatment

In an attempt to reduce the unacceptably high mortality from severe malaria, various adjunctive treatments for the complications of malaria have been made available (see [Table 4](#)).

2. It should be noted that the results of clinical trials with rectal artesunate relate to a single formulation and presentation that has well-characterized absorption kinetics; therefore, the results cannot necessarily be extrapolated to any other rectal formulation of artesunate. This product is being developed within the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases.

Table 4 Immediate clinical management of severe manifestations and complications of falciparum malaria

Manifestation/complication	Immediate management ^a
Coma (cerebral malaria)	Maintain airway, place patient on his or her side, exclude other treatable causes of coma (e.g. hypoglycaemia, bacterial meningitis); avoid harmful ancillary treatment such as corticosteroids, heparin and adrenaline; intubate if necessary.
Hyperpyrexia	Administer tepid sponging, fanning, cooling blanket and antipyretic drugs.
Convulsions	Maintain airways; treat promptly with intravenous or rectal diazepam or intramuscular paraldehyde.
Hypoglycaemia (blood glucose concentration of < 2.2 mmol/l; < 40 mg/100 ml)	Check blood glucose, correct hypoglycaemia and maintain with glucose-containing infusion.
Severe anaemia (haemoglobin < 5 g/100 ml or packed cell volume < 15%)	Transfuse with screened fresh whole blood. Prop patient up at an angle of 45°, give oxygen, give a diuretic, stop intravenous fluids, intubate and add positive end-expiratory pressure/continuous positive airway pressure in life-threatening hypoxaemia.
Acute pulmonary oedema ^b	
Acute renal failure	Exclude pre-renal causes, check fluid balance and urinary sodium; if in established renal failure add haemofiltration or haemodialysis, or if unavailable, peritoneal dialysis. The benefits of diuretics/dopamine in acute renal failure are not proven.
Spontaneous bleeding and coagulopathy	Transfuse with screened fresh whole blood (cryoprecipitate, fresh frozen plasma and platelets if available); give vitamin K injection.
Metabolic acidosis	
Shock	Exclude or treat hypoglycaemia, hypovolaemia and septicaemia. If severe, add haemofiltration or haemodialysis. Suspect septicaemia, take blood for cultures; give parenteral antimicrobials, correct haemodynamic disturbances.
Hyperparasitaemia	Non-immune patients with parasitaemia >20% should continue to receive parenteral therapy wherever possible, as there is no evidence for or against using oral treatment in this group and the risks are high. Alternatively, the first dose of artemisinin derivative can be given parenterally or rectally to ensure adequate absorption. Treatment must be monitored closely for the first 48 hours after initiating treatment.

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

b. Prevent by avoiding excess hydration.

4.4 Treatment during pregnancy

Pregnant women are at particular risk of *P. malariae* infection, with serious consequences for both the mother and the fetus. The clinical features and the consequences of malaria in pregnancy vary according to the transmission pattern. Pregnant women are at greater risk of developing severe malaria than other adults in areas of high to moderate transmission. In low-transmission areas, the risk for severe malaria is higher than in non-pregnant women, and the mother or her fetus might die from hypoglycaemia, cerebral malaria or severe anaemia. In areas of stable transmission, malaria has a greater impact during the first and second pregnancies. The parasite prevalence is higher than in non-pregnant women, but the infection is usually asymptomatic. The main consequences are low birth weight and maternal anaemia.

Malaria prevention and control during pregnancy require a three-pronged approach: effective case management of malaria infections, use of insecticide-treated bednets and intermittent preventive treatment in area of stable transmission.

In the management of uncomplicated malaria, during the first trimester, quinine is given with or without clindamycin. Where quinine is not available or there is no guarantee of compliance or tolerance, an ACT can and should be used. In the second and third trimesters, treat with the artemisinin-based combination treatment that is used in the country or the region.

The parenteral antimalarial treatment that is locally available for severe malaria should be given in full doses. In the first trimester, quinine and artesunate can be considered as options. In the second and third trimesters, where available, artesunate is the first option and artemether the second.

Intermittent preventive treatment is administration of a full therapeutic dose of a drug at predetermined intervals during pregnancy. This preventive strategy protects pregnant women from malaria and reduces the related consequences, namely low birth weight, anaemia and severe malaria. Currently, sulfadoxine-pyrimethamine is the treatment of choice. All pregnant women in areas of stable transmission should receive at least two doses of treatment with sulfadoxine-pyrimethamine during the second and third trimesters (after quickening). Intermittent preventive treatment should be given at least four weeks apart under direct observation at visits to antenatal clinics.

Women known to be HIV-positive should receive at least three doses of intermittent preventive treatment. If the prevalence of HIV among pregnant women is higher than 10%, the national policy should be to deliver three doses of preventive treatment during pregnancy. Treatment should not be given to HIV-positive pregnant women receiving daily cotrimoxazole. Treatment with sulfadoxine-pyrimethamine is contraindicated in cases of hypersensitivity to sulfonamides.

4.5 Home management of malaria

Health service coverage is low in many malaria-endemic countries, and many children and adults with fever are treated at home or close to home. In order to optimize the benefit of artemisinin-based combination treatments against malaria, the drugs must be available as widely as possible, i.e. at community level. Therefore, home management of malaria should be implemented in areas where there is poor access to health facilities, as the formal public health delivery system will not reach many persons who need treatment.

The dissemination of clear, national treatment guidelines, provision of adequately packaged and presented antimalarial agents, use of appropriate information, education and communication materials, and monitoring of deployment, access and coverage are needed to optimize the benefits of these new, effective treatments.

4.5.1 Uncomplicated malaria

The national malaria treatment policy should apply to both diagnosis and treatment in case management at community level. In areas where parasite-based diagnosis is used, community distributors can be trained to use rapid diagnostic tests and follow the guidelines used in peripheral health units.

The antimalarial medicines used as first-line treatment in the national treatment policy should also be used at community level. There is no need for a dual policy, as the artemisinin-based combination treatments currently recommended by WHO can easily be administered by community-based distributors.

4.5.2 Severe malaria

Caregivers should promptly recognize the signs and symptoms of severe disease, give pre-referral treatment with artesunate or artemisinin-based suppositories and refer patients to the nearest health facility for further evaluation and treatment. Community-based health providers should not keep these patients in the community, as they need further evaluation, treatment and supportive care, which are not available at community level.

5. Supply chain management and logistics

This section of the manual covers practical ways of ensuring that high-quality antimalarial medicines are available to the users continuously in adequate amounts. The uninterrupted availability of medicines in health facilities is one of the most fundamental components of an efficient case management system. It will save lives, improve health and promote trust and use of health services. As medicines are special commodities and are costly, efforts should be made to improve current systems for supply management. Incorrect quantification, improper storage and distribution resulting in the expiry of medicines seriously reduce the therapeutic benefits to patients.

As malaria is an acute and potentially fatal illness, essential antimalarial medicines must be available at all levels of the health care system, including remote rural areas at highest risk for malaria. Strengthening the supply management of antimalarial medicines can strengthen health services, because all essential medicines are managed and distributed together.

The four artemisinin-based combination therapies currently recommended by WHO as first-line treatment of falciparum malaria are available in three to four different course-of-therapy blister packs with two-year shelf lives. These features of the treatments raise logistic problems for medicine distribution and information management systems.

Antimalarial medicines, like all medicines, are subject to national systems of drug registration, which ensure that medicines approved for sale meet the criteria of efficacy, safety, quality and completeness of packaging information. Fixed-dose and co-packaged combination therapies must be registered even if the individual components are already registered in the country.

Existing laws and regulations that may limit the prescribing and dispensing of newly registered medicines to specially trained health professionals should be taken into account in planning home-based management of malaria. Use of trained drug sellers to provide early diagnosis and treatment of malaria near the home might be introduced as a research project approved by the national health authorities. The results of such demonstration projects within a country might help convince policy-makers to adopt new approaches, especially those requiring significant changes in policy and regulations that might require increased financial resources.

5.1 Quantification of drug requirements

The quantities of antimalarial medicines required can be estimated using the standard morbidity method or the consumption method, which are generally used for large-scale forecasting of drug requirements for annual or semi-annual procurement cycles. Before starting quantification by either method, the following steps must be completed:

- Nominate the official (senior pharmacist, medical officer or senior administrator) responsible for the quantification. A person(s) with experience in large-scale quantification of antimalarial drugs should be consulted at this stage.
- Form a coordination working group (composed of senior medical administrators or clinicians, managers of the health information system, pharmacists and a finance officer).
- Define the target coverage for the quantification (by geographical area and health facility or community level), specifically for medicines in the national malaria treatment policy.
- Consider whether the needs of the facilities for which drug requirements are being quantified are expanding or contracting, in the light of the health sector development plan of the country and the expected impact on consumption of antimalarial medicines of the policy on pricing and accessibility of medicines.
- Consider how the estimates will be affected by existing prescribing patterns (i.e. malaria treatment based on presumptive diagnosis) and the expected extent of change in prescribing practices (i.e. after introduction or expansion of malaria rapid diagnostic tests).
- Make a realistic plan for completion of the quantification, on the basis of whether it is to be centralized (managed at central level) or decentralized (each facility compiling its own estimates, which are reviewed and consolidated at the district and provincial levels before submission to the procurement office).

The last step is particularly relevant for decentralized systems, in which quantification is based on the consumption method.

5.1.1 Morbidity method

The morbidity method may be most appropriate for quantifying drug requirements if:

- the available consumption data are incomplete or unreliable;

- prescribing patterns are not cost-effective, and systematic improvement is required (e.g. persistent reliance on clinical diagnosis in all age groups despite the availability of microscopy and rapid diagnostic tests);
- the previous budget for drug procurement was insufficient to meet requirements; or
- the health facilities are new or rapidly expanding or a new antimalarial treatment is being introduced, so that past consumption data are not a reliable guide to future requirements.

This is the method of choice for estimating antimalarial drug requirements in countries in the early phase of implementation of artemisinin-based combination treatments.

Step 1. Prepare a list of drugs to be quantified

The list should contain the antimalarial medicines in the national guidelines for treatment of falciparum malaria (both uncomplicated and severe) and the other species (see [Table 5](#)).

Step 2. Establish the standard treatment course

Standard treatment courses across the range of different age groups must be established. It is preferable to calculate average regimens, on the basis of observed or reported practices, to make the estimate of requirements more realistic. As these data are often not available, the ideal regimens from standard treatment guidelines are generally used in the morbidity method.

The standard courses of treatment are shown for *P. vivax* malaria in [Table 6](#), for uncomplicated falciparum malaria during the first trimester of pregnancy and for intermittent preventive treatment with sulfadoxine-pyrimethamine in [Table 7](#), and for severe malaria in [Table 8](#). The correlations between age and weight should be derived from national data that reflect the actual anthropometric and nutritional status of the population.

Step 3. Estimate the number of malaria episodes requiring treatment in health facilities

The morbidity method requires information on the population by age group; the actual or projected incidence of malaria; patient attendance at health facilities; and malaria treatment practices (actual or expected). Information from the routine health management information system is often incomplete or not available, and special surveys of representative samples of health facilities might not be possible. It may therefore be necessary, instead, to estimate patient contacts with health facilities that result in malaria treatment.

Table 5 WHO-recommended first- and second-line treatments for uncomplicated malaria and treatment for severe malaria

	<i>P. falciparum</i>	<i>P. vivax</i>	<i>P. malariae</i>	<i>P. ovale</i>
Uncomplicated	AL		CQ	CQ
– first line	AS+AQ AS+MQ AS+SP	CQ Primaquine		
– second line	AL QNN	AQ Primaquine		
Severe	AS i.v./i.m. AM i.m. QNN i.v./i.m. AT i.m.			

Table 6 Dosing schedule for chloroquine, amodiaquine and primaquine for treatment of *P. vivax* malaria

Age	< 4 m.	4–11m.	1–2 y.	3–4 y.	5–7 y.	8–10 y.	11–13 y.	>14 y.
Weight (kg)	5–6	7–10	11–14	15–18	19–24	25–35	36–50	> 50
Medicine (strength)								
CQ (daily dose)								
• 100 mg base tabs								
• 150 mg base tabs								
• 50 mg base/5 ml								
AQ (daily x 3 days)								
• 153 mg base tabs								
• 200 mg base tabs								
PQ (daily x 14 days)								
• 5 mg base tabs								
• 7.5 mg base tabs								
• 15 mg base tabs								

Table 7 Standard treatment courses for treatment of uncomplicated falciparum malaria during the first trimester of pregnancy, and for intermittent preventive treatment with sulfadoxine-pyrimethamine

Medicine	Daily dose (tablets)	Duration of treatment	Total tablets per treatment
Quinine sulfate 300 mg tabs	2 tabs x 3 times daily	7 days	42 tabs
Sulfadoxine-pyrimethamine 500/25 mg tabs	3 tabs in single daily dose	repeated 3 times (2 nd and 3 rd trimesters)	9 tabs

AL = artemether-lumefantrine; AS = artesunate; AQ = amodiaquine; CQ = chloroquine; M = mefloquine; SP = sulfadoxine-pyrimethamine; QNN = quinine; IPT = intermittent preventive treatment; AM = artemether; AT = artemotil. m. = month; y. = year

Table 8 Standard treatment courses for treatment of severe malaria, both the loading dose and the maintenance dose to be repeated during the first 48 hours of treatment

Age Weight (kg)	< 4 m. 5–6	4–11 m. 7–10	1–2 y. 11–14	3–4 y. 15–18	5–7 y. 19–24	8–10 y. 25–35	11–13 y. 36–50	>14 y. 50+
Medicine (strength)								
Artesunate								
Loading dose								
Maintenance (first 72 hours)								
Artemether i.m.								
Loading dose								
Maintenance								
Quinine								
Loading dose								
Maintenance								

Table 9 An example of calculation of requirements of artesunate plus sulfadoxine-pyrimethamine or artesunate plus mefloquine in areas of intense malaria transmission

Age group (years)	Population (a)	Febrile episodes per year treated as malaria (b)	Percentage attendance at health facility (c)	Percentage treated after lab diagnosis (d)	No. treatment courses (e)
<1	6 000	2	0.50	1.0	6 000
≥2–6	16 000	4	0.50	0.95	30 400
≥7–13	25 000	2	0.40	0.90	18 000
>14	53 000	1	0.20	0.80	8 480
Total	100 000				62 880

Table 10 An example of calculation of requirements of artemether-lumefantrine in areas of low malaria transmission

Age group (years)	Population (a)	Febrile episodes per year treated as malaria (b)	Percentage attendance at health facility (c)	Percentage treated after lab diagnosis (d)	No. treatment courses (e)
<3	11 000	0.50	0.50	0.50	1 375
3–8	17 000	0.50	0.50	0.50	2 125
9–14	21 000	0.25	0.40	0.50	1 050
>14	51 000	0.25	0.20	0.50	1 275
Total	100 000				5 825

Step 4. Calculate the quantities of medicines for each type of standard malaria treatment

The expected frequency of malaria episodes per age group treated in health facilities is multiplied by the amount of antimalarial medicine required per corresponding age group, estimated on the basis of the national malaria treatment guidelines. The expected requirement of each drug is the sum of the needs estimated for each age group. An example of calculation of the requirements for artesunate plus sulfadoxine-pyrimethamine or artesunate plus mefloquine in areas of intense transmission is given in **Table 9**. The total number of treatment courses needed for each age group, e , is obtained by multiplying the number of febrile episodes expected to be treated as malaria ($a \times b$), adjusted by the percentage coverage offered by the health facilities served by the drug distribution system, c . The extent of reduction of treatment due to laboratory confirmation of diagnosis, d , should also be taken into consideration depending on coverage by laboratory services (microscopy and rapid diagnostic tests) and expected compliance with negative results by health providers (see below).

Example:

In the 7–13 age group

The total number of febrile episodes expected to be treated as malaria =
 $(a \times b) = 25\,000 \times 2 = 50\,000 \dots$ but ...

The number of episodes expected to be seen in health facilities =
 $50\,000 \times c = 50\,000 \times 0.4 = 20\,000 \dots$

however, after laboratory confirmation

The number of episodes to be treated (e) =
 $20\,000 \times d = 20\,000 \times 0.9 = 18\,000$

An example of calculation of the requirements for artemether-lumefantrine in areas of low transmission is given in **Table 10**. The method of calculation and the factors are the same as for **Table 9**.

The morbidity method allows estimation of total requirements in medicines for large-scale forecasting, as part of annual procurement cycles. The estimates obtained using this method should be compared with estimates derived from the consumption method, even if they are based on a sample of health facilities

with good stock records. This can indicate the actual drug delivery capacity of the health facilities and might lead to reconsideration of some of the assumptions made for the morbidity estimates.

For special life-saving and relatively expensive medicines, i.e. those used for the management of severe malaria (Table 8), estimates must be based on both morbidity records (number of malaria inpatients) and previous consumption data (even if based on a sample of health services with inpatient facilities). In countries where parenteral artemisinin formulations have been introduced recently, for which consumption data are not available, the consumption of quinine ampoules can be used to estimate the requirements for artesunate or artemether ampoules. This requires conversion into equivalent amounts of parenteral treatment courses for adults for both medicines, according to the following formulas (derived from Table 8).

5.1.2 Consumption method

The consumption method is based on records of past consumption of individual drugs, adjusted by stock-outs and projected changes in drug use. The method requires inventory records of past consumption for all drugs eligible for procurement. If the records of past consumption are accurate and rational, this method gives an adequate prediction of future needs and is the method of choice in large, well-established drug supply systems with long experience of uninterrupted supply.

Since malaria transmission is seasonal, consumption data for the past 12 months should be reviewed. If drug requirements are to be estimated for a six-month period (semi-annual procurement cycle), the consumption data for the same six-month period of the previous year must be used. The most accurate records are stock records and distribution reports from central, regional and district warehouses.

Consumption is calculated from these records as:

$$\text{Total consumption (for a specified period)} = \text{opening stock} + \text{medicines received} - \text{closing stock}$$

Dispensing records from health facilities could also be used, in principle, but this approach is reliable only if records are well kept and complete. It might be difficult to obtain consumption data from patient registers, even if treatments are recorded, because this information is not routinely reported in health management information systems.

Records of stock-outs are important for calculating consumption precisely. The simplest approach is to divide the total consumption by the number of months reviewed and correct by the average number of months of stock rupture, as follows:

$$\text{Adjusted average monthly consumption} = \frac{\text{consumption during the review period}}{\text{No. of months in review period} - \text{No. of months of stock-out in review period}}$$

5.2 Management of routine ordering

5.2.1 Quantification of annual requirements

Once the initial quantification has been completed by the morbidity or the consumption method, the following steps must be completed to convert the estimated drug requirements into potential orders.

- Estimate requirements on the basis of the number of supply points at each level, their frequency of requisition and delivery, the amount of safety stock at each level, in line with the overall plan of starting and expanding the distribution of antimalarial medicines.
- Consider the impact of lead time, including time to place an order, production time, time for shipment, customs clearance and arrival in the central warehouse.
- Adjust the amounts for damage, spoilage, expiration and theft; many systems allow at least 10% for losses. A percentage of loss must be allowed in quantifying vital items: artemisinin-based combination treatments are more attractive to thieves than other medicines because of their high price in the private sector.
- Adjust the quantity to be ordered according to pack size (multiples of 25, 30 or 50 individual treatment units, according to the supplier), as well as the minimal order size required by the supplier.
- Estimate total procurement costs on the basis of current drug prices from local suppliers and international procurement agencies.
- Adjust the estimated budget for expected price increases due to anticipated international devaluation, devaluation of local currency and possible increases in shipping costs.
- Reduce the estimated quantities to conform to budget realities, if necessary.

5.2.2 Calculation of safety stocks

In order to convert the estimated drug requirements into potential orders to cover consumption between two cycles of orders from the same supplier, the amount of medicines that must be held in stock should be calculated. As it is impossible to forecast demand with complete accuracy or to be certain about the supplier's performance, a certain amount of medicine must be stocked to absorb fluctuations in supply and demand and to reduce the risk for stock-outs. High stock levels, however, increase inventory costs (personnel, storage, risks of spoilage, expiry and theft), and most public pharmaceutical systems calculate the minimum safety stock needed to protect against stock ruptures.

The commonest method for estimating safety stock needs is to determine the average lead time for each item from the current supplier (interval from the time the order is placed to the time the medicines reach the central warehouse) and the average consumption. Invoices from suppliers can be used to calculate the average lead time for the last few procurements. The safety stock is calculated by multiplying the adjusted average monthly consumption by the expected lead time, as follows:

$$SS = Ca \times LT,$$

where:

SS is the safety stock, *Ca* is the average monthly consumption, adjusted for stock rupture, and *LT* is the lead time between initiation of purchase order and receipt of medicines in the warehouse, also calculated in months.

The safety stocks of vital items must be increased when consumption varies or when the lead time is uncertain. The simplest approach is to add an arbitrary multiplier to the basic formula, for example, to multiply the safety stock by 1.5.

A public drug distribution system generally has three types of stores: one or more primary stores, which receive purchases and generally serve a whole country, region or province; intermediate stores, which receive the medicines distributed by the primary stores and are often on the site of a regional or district hospital; and health facility stores, which receive the medicines distributed by the intermediate stores. The physical size of the store at each level is determined by the demand for drugs and by the supply frequency. The stock levels within the supply system and the number of supply points at each level constitute the supply pipeline. The number of levels, the frequency of requisition and delivery and the amount of safety stock at each level will influence the amount of medicines needed to fill the supply pipeline.

5.2.3 Time and quantity for re-ordering

A new order should be placed once the stock has reached a minimal level. In many situations, the minimal stock level (re-order level) is calculated in the same way as the safety stock, i.e. by multiplying the average lead time by the average quantity consumed during the same period.

Once the basic inventory has been established, the question is how much medicine should be ordered. Several formulas are available, but one of the most commonly used is the consumption-based re-ordering formula, in which the quantity of medicines to re-order is based on the adjusted average monthly consumption multiplied by the sum of the lead time and procurement period plus the safety stock level, after removal of stock on order and stock in inventory. This is expressed as:

$$Q_o = Ca \times (LT + PP) + SS - (S_i + S_o),$$

where:

Q_o is the quantity of medicines to be re-ordered in the next procurement period; Ca is the average monthly consumption, adjusted for stock rupture; LT is the lead time; PP is the procurement period; SS is the safety stock; S_i is the stock in inventory, i.e. the working stock plus the safety stock; and S_o is the stock on order but not yet received.

As artemisinin-based combination treatments are available in three to four different course-of-therapy blister packs, calculation of the quantities to re-order requires a review of the consumption (from stock records) of each type of blister pack, adjusted for stock rupture.

Ordering also requires forecasts of future needs, the least predictable variable in a re-ordering formula. The amounts calculated from the formula should be adjusted for the expected seasonality of malaria or epidemic risk. If annual purchasing is for staggered deliveries or scheduled purchasing (e.g. at six-month intervals), the order to be delivered before the malaria transmission season should be increased, on the basis of consumption during the last comparable season. Consumption of antimalarial medicines during the four-month malaria transmission season can represent 60–70% of annual consumption.

In countries prone to epidemics of malaria, an appropriate epidemic stock of antimalarial medicines must be added to the quantities to be re-ordered. The history and extent of past malaria epidemics and their geography (epidemic-prone districts) will guide the amount and strategic placement of such stocks. Because of the relatively short shelf-life of artemisinin-based combination therapies (generally 18–20 months residual shelf-life at port of entry), the epidemic stock must be rotated with the routine stock to avoid the risk of expiration of medicines with a short shelf-life.

5.3 Managing distribution

Storage and distribution costs represent a significant component of the health budget, and transport costs can be very high, especially in large countries with low population densities. In many endemic countries, a six- or three-month re-order interval (or annual orders with staggered deliveries at six- or three-month intervals) is useful for reducing inventory costs for artemisinin-based combination treatments. This also allows regular replenishment of the inventory with new supplies with adequate residual shelf-life.

Staggered deliveries make it possible to manage the distribution of smaller amounts of artemisinin-based combination treatments, which might be appropriate in countries in the early phase of implementation, with limited experience in the inventory and distribution of high-value medicines available in different course-of-therapy blister packs with a relatively limited shelf-life. To a certain extent, staggered delivery gives the requisitioner flexibility to adjust deliveries in cases of high inventory levels due to unexpectedly low consumption or difficulties in distribution. Reduction is generally easier than increase, as the production of artemisinin-based combination treatment is generally complex. Repeated requests for delay or reduction of expected deliveries can, however, be a cause for litigation, as suppliers might ask to be reimbursed for unanticipated warehousing costs.

Artemisinin-based combination treatments may initially be distributed by a “push” system, in which the central level determines the quantities of medicines to be delivered to lower levels. This system is useful if peripheral staff has limited experience in assessing needs and managing an inventory of these new medicines and there is uncertainty about demand exceeding the supply (making rationing necessary).

The next step is to select an appropriate re-supply interval. Generally, deliveries are made at intervals of one to three months, depending on availability, capacity and transport costs, as well as order size and storage capacity at each level of the distribution system. Other factors, such as expiry dates and security against theft, should also be taken into consideration in selecting appropriate re-supply intervals.

In the management of the distribution of malaria medicines, both the seasonality of malaria and the reliability of transport during the rainy season should be taken into account. Delivery frequency and volume must be scheduled to work around road interruptions due to rain. In remote areas that are difficult to reach, adequate supplies of artemisinin-based combination treatments must be delivered and stored at least one month before the start of the malaria season, in locally accessible warehouses, preferably in health facilities.

A detailed plan must be drawn up of the time required for processing requisitions and organizing deliveries at each level of medical store, including the time required for transport. One practical approach to planning such requirements is to calculate the number of days per month needed for processing requisitions and deliveries at each distribution level (from central to intermediate warehouses up to health facility stores) and to mark the requirements in days on a planning chart. This detailed plan should include the time required for preparing deliveries and organizing transport before the rainy season for destinations with poor access.

5.4 *Medicine management information system in health facilities*

A reliable management information system is vital for coordinating a drug distribution network. It is a recording and reporting system for inventories, costs, receipt and issue of medicines. Therefore, the forms, records and reports form the core of the supply information system, carrying specific information on medicine needs, movement and associated financial transactions.

The most important is the stock record of each item in the inventory. At a minimum, there should be a space on the form to describe each item (one for each course-of-therapy blister pack in the case of artemisinin-based combination treatments), its stock reference number and unit of issue (e.g. boxes of 30 treatment units). The stock record documents all transactions related to an item. Columns and rows appear below the standard information to record the source of each delivery and the particular health facility to which each item was issued, the quantities received and issued, the balance and the expiry date of each new lot received. Some stock records contain additional information, such as re-order level, re-order interval, re-order quantity, lead time and estimated consumption rate. Many variations exist, but the sample stock record shown below (Figure 6) contains the most important features.

For artemisinin-based combination treatments, separate stock record cards should be maintained for each course-of-therapy blister pack in its unit of presentation (e.g. Coartem® is available in dispenser boxes containing 30 individual treatment courses). To facilitate stock inventory control, the stock record form should state the number of boxes and not the individual treatment courses. The medical store unit must make regular, periodic counts of the actual stock on hand to ensure that the stock balance on the inventory records is correct. Both active and safety stocks in all locations should be counted as scheduled and compared with the numbers on the respective cards.

GENERIC NAME: *artemether-lumefantrine* STRENGTH: *20 mg/120 mg*
 INVENTORY NUMBER: *xxxxx* DOSAGE FORM: *tablet*
 UNIT OF ISSUE: *6 x 2 tablets x 30* UNIT PRICE: *US\$ 42.-*

Date	Source or Recipient	Quantity received	Quantity issued	Balance	Expiry date	Signature
15/9/05	Inventory			120	06/2006	
17/9/05	Clinic A		10			
23/9/05	HC A		30			
25/9/05	Clinic B		10			
26/9/05	Clinic C		10			
1/10/05	Hospital		40			
3/10/05	HP A		5			
3/10/05	CMS	400			07/2007	
5/10/05	Clinic B		10		06/2006	
8/10/05	HC A		30		5-06/2006 25-07/2007	
12/10/05	Clinic A		10			
15/10/05	Clinic C		10			
23/10/05	Hospital		40			
29/10/05	HP B		5			
1/11/05	HP A		5			
				305		

HC = health centre; HP = health post; CMS = central medical store.

Figure 6 Example of a stock record card

The stock record form makes it possible to calculate consumption over a certain period, according to the method described in section 5.1.2 (consumption = opening stock + medicines received - closing stock). In the example shown in **figure 6**, consumption during the period 15 September 2005 to 1 November 2005 was $120 + 400 - 305 = 215$ unit forms (i.e. $215 \times 30 = 6450$ individual treatment courses). The stock record card can be used to calculate monthly consumption: consumption in October 2005 in the example was $60 + 400 - 355 = 105$ unit forms (i.e. $105 \times 30 = 3150$ individual treatment courses).

The stock record card in the example refers to paediatric doses of artemether-lumefantrine (15–25 kg of body weight) in a district medical store receiving medicine from a central medical store and delivering it to the hospital, health centres, several clinics and health posts. As standard amounts of medicines are delivered according to health facility level (clinics, 10 boxes; health posts,

5 boxes), the system in use in this example is probably a “push” system, whereby drug allocations for distribution are determined according to the expected consumption at peripheral level. While no stock ruptures are recorded on this stock record card, it is important to evaluate the stores of health facilities, as stock rupture is more likely in a “push” than in a “pull” system guided by consumption patterns at peripheral health facilities.

As individual health facilities are the end-users of medical supplies, it is essential to maintain information from those facilities in order to monitor consumption. Various methods of calculating re-order quantities exist (including that described in section 5.2.3), but they are all based on monthly consumption. Monthly consumption is determined from the stock card and recorded on a monthly stock recording form. An example of a monthly stock management form for medicines and laboratory supplies is shown in [Annex 1](#).

Individual health facilities report to district offices, which report to regional offices, which report to the central office. The reports are used to assess drug use, to project drug needs and to revise budgets. Their ultimate goal is managing the reliable movement of supplies from the source to the end-user the least expensively and to protect stored items from loss, damage, theft or waste. The success of the information system depends primarily on well-trained, well-organized and well-supervised staff.

5.5 Quantification of rapid diagnostic test requirements

Many countries are introducing rapid tests for the diagnosis of malaria to extend parasitological confirmation of malaria to areas and health facilities where there is no microscopy. As these tests are relatively new, relatively expensive and have a limited shelf-life (a maximum of two years), quantification of the requirements for these rapid diagnostic tests needs special attention. Before quantifying the requirements for the public sector, it is important to:

- define the target coverage for quantification, indicating by geographical area the number of health facilities that will be using the tests, stratified by health care system level (hospitals, health centres, clinics, dispensaries, health units, health posts);
- consider whether the number of health facilities for which requirements are being quantified will be increasing or decreasing during the period covered by the quantification, as part of health sector development in the country;
- provide preliminary estimates of expected variations in the use of health facilities after the introduction of the new malaria treatment policy and the

expected impact of the policy on pricing, access to medicines and on health service utilization.

In countries where rapid diagnostic tests have been introduced, consumption data from selected districts or regions where both the tests and artemisinin-based combination treatment are deployed should be used to estimate requirements for rapid diagnostic tests. Consumption data should preferably cover at least two years after introduction. If the consumption data are from areas prone to malaria epidemics, the likelihood that fewer rapid diagnostic tests might be required in normal years should be considered.

In countries where rapid diagnostic tests have never been used, alternative methods for estimating requirements must be used, based on the principle that a rapid diagnostic test is required where microscopy is not available. The public sector demand can be estimated from records of the number of febrile patients treated for malaria (i.e. the number of probable malaria cases) for whom no microscopy was performed in public health services. In practice, the overall demand of the public sector for rapid diagnostic tests can be estimated by subtracting the total number of cases examined by microscopy from the total number of reported cases of malaria in public health facilities.

If rapid diagnostic tests are to be used at all levels of the health care system, the following formula should be applied to data for the most recent calendar year:

$$\begin{aligned} \text{Public sector rapid diagnostic test demand} = \\ \text{number of malaria cases reported} - \\ \text{number of microscopy examinations for malaria} \end{aligned}$$

The estimated demand for rapid diagnostic tests must then be adjusted by the completeness of reporting and the target proportion of patients with probable malaria to be tested.

Completeness of reporting can vary according to health facility level. If high-level health facilities (i.e. hospitals and health centres with microscopy capability) have more complete reporting than lower-level health facilities, the estimated need for rapid diagnostic tests will be artificially reduced, or underestimated. If possible, the total number of malaria cases should be corrected for completeness of reporting, by dividing the total number by the proportion of health facilities, of all existing facilities, that report data within a nationally established time frame.

Because of the specific programmatic requirements for rapid diagnostic testing, including training, maintenance of the cold chain and quality assurance, quantification of requirements should be adjusted to meet the needs of

the operational plans set by the malaria programme. In most situations, rapid diagnostic tests will not be used at all levels of the health care system, some health facility levels might not be included at the time of introduction of the tests, and operational coverage might increase over time. For example, if peripheral health posts are initially not included and 20% of the reported cases of malaria are treated at this level, the overall requirement for rapid diagnostic tests should be reduced proportionally by 20%. Some countries might plan to use rapid diagnostic tests in all health facilities without microscopy, while others might plan to use them as part of home-based management. Estimates of requirements at community level should take into account the expected number of fever episodes that will be tested by community-based health providers over a certain period as part of the operational plan for community-based malaria case management.

6. Quality assurance of malaria diagnosis and antimalarial medicines

6.1 Microscopy

Traditional microscopy is most reliable in an expert's hands, but it is much less sensitive and precise in routine practice, due to errors in collection, processing or examination of slides, and in judgement and reporting. The sources of errors are many and depend on the competence of laboratory technicians, physical limitations in the workplace, the quality of supplies, the condition of microscopes and workload.

Quality assurance programmes for traditional microscopy, developed in the 1950s and 1960s, emphasized validation by the re-checking of slides by expert or senior microscopists. The main activity was re-examination of all positive slides and a random sample (10%) of negative ones. Less importance was accorded to species identification, and there was no emphasis on quantification. In some settings, cross-checking is blinded, and feedback, if sent, refers only to discrepancies in positivity and species identification, not to the quality

of slide processing. Routine systems do not provide for continuous monitoring of individual technicians and laboratories.

While competency testing is the main method for assessing technicians, it is used in only a few settings. Validation of slides read is commoner and allows for monitoring of performance over time and detection of additional problems, such as poor staining, poor slide preparation, inadequate supplies and equipment and other factors affecting performance in malaria microscopy. The currently recommended practical method is regular evaluation of the proportion of agreement between first reading and expert re-examination of at least 10 slides per month (5 randomly selected positive slides and 5 randomly selected negative slides). These numbers are manageable in most settings, and validators can cope with the workload.

Poor performance detected by slide cross-checking can be remedied by a variety of strategies, such as retraining, regular consultative visits and improving supplies and equipment, depending on the type of problem identified. Continuous monitoring and evaluation of individual laboratories and technicians should be established by means of a supervisory checklist. Annex 2 shows a model checklist for malaria laboratory supervision. The quality of microscopes, the quality of reagents and training of staff in quality assurance in central and peripheral laboratories should be assured at national or subnational level. Technicians should be trained to detect malfunctioning microscopes and to use simple methods for minor repairs. They should also be able to recognize errors in processing slides and know how to prevent them.

A quality assurance system required a national reference laboratory or centre for setting standard operating procedures and providing training and reference materials, including banks of both good and bad slides and a competent workforce of senior microscopists and trainers. A functional quality assurance system requires additional investment, which may be offset by improved cost-effectiveness of malaria diagnosis and improved confidence of health workers in the results of microscopy.

6.2 Rapid diagnostic tests

Antigen-detecting rapid diagnostic tests are important for parasitological confirmation of a diagnosis of malaria when microscopy is not available. Many tests are sold commercially, but most can be used to detect only *P. falciparum* antigens (histidine-rich protein II [HRP-II] and plasmodium lactate dehydrogenase) or a combination of *P. falciparum* antigens (HRP-II) and antigens common to all parasite species (plasmodium lactate dehydrogenase and aldolase).

Rapid diagnostic tests are affected by various conditions of manufacture, storage and use, which can impair their accuracy and reliability. They are also subject to degradation by heat and moisture, and most manufacturers specify storage at 4 °C–30 °C. The tests should be stored centrally, in air-conditioned facilities when possible. Storage in the field should be under similar conditions to those used for drugs. Transport in the sun in non-air-conditioned vehicles and the length of storage in remote locations should be minimized.

Quality assurance must become an integral part of the budgets and implementation plans for use of rapid diagnostic tests. The aim is to ensure the accuracy of the tests in the hands of the end-users. Quality assurance includes monitoring the technical standard of the tests, post-purchase testing of a sample of tests, training and supervision of users and control of storage and transport to minimize unfavourable environmental effects.

Health workers should know how to manage negative results, as rapid diagnostic tests are not infallible, even when prepared and interpreted correctly. A clinical algorithm should be designed for treatment of patients with negative results but who have symptoms of severe malaria, while other causes of illnesses are being investigated.

In order to assess the quality of rapid diagnostic tests that have had typical storage and distribution in remote areas, the results should be compared with those of microscopy at a few sentinel sites, with slides stained on site and checked centrally. The person in charge of quality assurance should also be in charge of monitoring results.

The preparation and interpretation of rapid diagnostic tests by health workers should be monitored three to six months after training, and remedial training should be given as required. During supervisory visits, interpretation of a set of prepared rapid diagnostic tests should be re-tested, and the preparation technique should be assessed; diagnosis and treatment records should be reviewed.

6.3 Antimalarial medicines

Quality assurance generally includes all activities and responsibilities required to ensure that pharmaceutical products meet quality specifications in their final dosage form. Good manufacturing practice is an aspect of quality assurance that ensures that products are consistently produced and controlled to the standards appropriate to their use and to the standards required by the drug regulatory authority. The main aim of good manufacturing practice is to diminish the risk, inherent in any pharmaceutical production, of unexpected

cross-contamination, incorrect labelling or human error. WHO has consolidated the good manufacturing practices of various countries into a single, standardized list, applicable to local manufacturers in developing countries.

Quality control is the part of good manufacturing practice that addresses operations and decisions about the quality of a product. In particular, quality control involves sampling, specifications, testing and documentation and procedures to ensure that the necessary tests are carried out and that materials are not released for use, sale or supply until their quality has been judged to be satisfactory.

Samples for quality control should be collected as close to the end-user as possible and sent for analysis to well-recognized reference laboratories at national or regional level. A two-level system of testing can be used, with basic testing at sentinel sites at the periphery, and the sending of 100% of failed or doubtful samples and 5–10% of passed samples to the national reference laboratory for verification.

Simple test methods are available for quality assurance of pharmaceuticals under field conditions, for rapid detection of counterfeit and substandard pharmaceuticals. Some are commercially available and assembled in self-contained kits in suitcases. These systems allow basic quality control of selected essential medicines, including artemether and artesunate, with sufficient supplies to run 1000–3000 tests. Testing includes both physical testing (visual inspection and tablet or capsule disintegration test) for rapid rejection of counterfeits and preliminary assessment of drug solubility and availability, and chemical analysis (simplified colour reactions and semiquantitative thin-layer chromatography tests) for rapid checking of a drug's identity and for semiquantitative analysis of the amount of drug present.

7. Training health workers

Effective disease management requires prompt diagnosis and correct treatment with effective antimalarial medicines and supportive management. A critical mass of competent health workers is needed with adequate skills to diagnose and treat malaria in both the public and the private health sector. They should be supported by community education for early recognition and health-seeking behaviour to ensure early treatment and referral. Collaboration

between malaria control programmes and service delivery programmes, such as those for the Integrated Management of Childhood Illness and reproductive health, should be encouraged.

7.1 Main training areas in malaria case management

Main areas in which training in malaria case management is needed:

- laboratory diagnosis, including microscopy, rapid diagnostic tests and quality assurance;
- treatment of uncomplicated and severe malaria;
- monitoring drug efficacy;
- supply and management of drugs and diagnostics and other logistics;
- use of the health management information system, including filling in data collection forms, data analysis and reporting on programme indicators.

7.2 Health workers to be trained

The first step is to identify the health care personnel involved in delivering malaria case management that are to be trained. The main group comprises health workers at all levels who provide treatment to patients with fever or malaria, including public-sector health care providers at district or local level, and private practitioners, who treat a substantial portion of malaria cases. Laboratory technicians, personnel responsible for supply and logistics management and personnel responsible for data collection, analysis and reporting also require training, as do community health workers and community volunteers.

Training partners might include private companies that provide services through employee health programmes, drug companies and pharmacists, community leaders, drug vendors, nongovernmental organizations, religious groups, traditional healers, schoolteachers and women's groups.

7.3 Training tools

The second step is to design training tools, based on national treatment guidelines, adapted to different categories of health care personnel. Standardized national training modules and training materials and consistent educational

messages, educational materials and teaching tools are needed for training specific target groups. The guidelines for training in the Integrated Management of Childhood Illness could be reviewed and adapted for this purpose. Health workers and village volunteers should be trained in communication skills.

Thirdly, the teaching curricula on malaria case management in medical and paramedical institutions and nursing schools should be reviewed and updated.

Lastly, a training plan should be drawn up, with continuing medical education for both pre-service and in-service personnel.

7.4 Training methods

Two training methods can be used: centralized group training using a cascade approach and individual health facility training, depending on the number of persons to be trained, the length of training and the availability of trainers. The first starts with a group of trainers of trainers, who in turn train groups of health workers at the provincial or district level at a centralized location. In individual health facility training, health workers are trained at their own health facility.

A follow-up supervisory visit to every trained health worker should be part of the case management training plan and budget. Ideally, the first follow-up supervisory visit should take place four to six weeks after the training session. This should be followed up by a system for reinforcing the skills acquired by the health worker, for example, refresher training, support and supervision, monitoring and evaluation of clinical skills, and the provision of feedback to the trained health workers.

8. Communication for behavioural change

Communication for behavioural change is used to encourage target populations to adopt appropriate behaviour. Interventions can be combined, depending on the local situation and the characteristics of the target group. The strategies include involving the community, village leaders, village health volunteers, representatives of mass organizations, including youth leagues, women's unions, schoolteachers and religious leaders. A peer education project could be mounted. Other strategies include social mobilization, advocacy and the use of mass communication (radio, television, traditional performances and printed media).

The relationship between knowledge and action is complex. People might be willing to try something different (for example, to see a health worker when they have a fever) or might resist new ways, depending on how strongly they hold their beliefs, how strictly they observe customs and how significant the problem is to their lives. Communication for behavioural change requires careful planning, taking into account all the other components of a malaria control programme (e.g. rapid diagnostic tests, artemisinin-based combination treatment, and bednets). In the process of trying new actions, people gain better understanding and experience, which could nurture acceptance and the adoption of new practices.

8.1 Country-specific communication strategy

An effective communication strategy is the key to appropriate health-seeking behaviour. The strategy must be multifocal, targeting individuals, households and communities, as well as public and community health workers. It must be designed to improve understanding of individual behaviour and practices as a basis for reinforcing positive behaviour and modifying less beneficial actions. Health education and community involvement are important to proper malaria case management. A critical mass of facilitators and community mobilizers should be trained in various aspects of malaria prevention and control, including communication skills. These skills could be integrated into other programmes, such as the Integrated Management of Childhood Illness, family planning and HIV/AIDS programmes, in order to reduce costs and allow the rapid expansion of a pool of trainers.

The steps to be considered in planning an effective communication strategy are:

Step 1. Identify risk factors

Knowledge, attitudes, practices and beliefs about prevention and seeking diagnosis and appropriate treatment should be identified through an analysis of existing studies of malaria prevention and control and reports on lessons learnt and best practices. A small survey could also be conducted.

Step 2. Identify target populations

People will be reached more effectively when information and messages are tailored to their needs. The primary target population might be children under five years of age, pregnant women, schoolchildren, legal and illegal migrants, farmers, foresters or community leaders. Secondary target groups are those who influence or deliver information to the primary population, such as community leaders, village health workers, malaria control officers, local health workers, peer educators, pharmacists, religious leaders and schoolteachers.

Step 3. Identify the desired behaviour and attitude changes

Decide which behaviour and attitudes should be addressed to help your target group to lower their risk for malaria infection. Recognize and plan for improvement in three key areas:

- personal commitment to make a change, by raising awareness about the extended effects of malaria infection on patients and their families and on the community's socioeconomic situation;
- acquiring knowledge and skills to bring about change, for example, properly impregnating bednets, taking antimalarial medicines optimally;
- creation of a supportive environment in which to make changes, for example, improving the availability and price of quality bednets, insecticide for impregnating bednets and antimalarial drugs.

Step 4. Design messages

When the target populations and the risk factors have been identified and the goals and objectives have been set, the next step is to design messages that will appeal to the target groups. The target groups should be involved in this step, to give the programme staff a better understanding of attitudes and to teach them to work with the target groups. Existing messages and materials could be re-used or adapted.

The key messages include seeking proper care if a fever develops; seeking proper care and medicines from a recognized, trained service provider; taking the right medicine for age or weight, as directed by the service provider; and finishing a treatment course. These messages should be adapted to the situation and needs of the target groups and should be prepared in all the appropriate languages for the country.

Step 5. Identify communication channels and media

The appropriate channels should be determined and messages designed for the type of communication media that will be most effective in reaching the target groups. These can include interpersonal communication, and print, audio and video media. Interpersonal communication is continuous and is driven by the requirements of the target population.

Key messages should be designed for dissemination via radio, television, newspapers and theatre to promote health-seeking behaviour and compliance with artemisinin-based combination treatments, with full community participation. Repeated input must be ensured, the impact must be monitored and new themes or presentation formats should be developed for messages over time. Special events and other interventions could also be considered. Combinations of these methods are the most effective, as they can reinforce each other.

Various channels of communication can be used to deliver messages:

- television, which has a primary role in advocacy and in reinforcing messages sent through various channels for behavioural change;
- participatory community radio, for regular updating of information on malaria and other health issues by various partners, including audiences, and for reporting improvements in living conditions as a result of malaria prevention and control, with various audio formats (spots, drama, documentary, songs) to suit local sociocultural and economic conditions, including local languages and terminologies;
- print media, such as posters, pamphlets and leaflets, developed with the participation of target groups and local health workers and the community, including innovative print materials, such as pictures, to educate specific target groups (e.g. illiterate persons);
- innovative methods, e.g. games for children and adults, and campaigns for malaria control in communities and schools, with child-to-child and child-to-community approaches for educating and mobilizing the community;

- a group consisting of district and local health personnel and malaria partners to educate, mobilize and support village volunteers in malaria control, with activities planned to suit the local situation, including service delivery;
- advocacy, building partnerships with politicians, decision-makers, donors, nongovernmental organizations and other resource providers to ensure that the political commitment and resources required for implementation are forthcoming.

Step 6. Pre-testing materials

All materials, whether new or adapted, must be pre-tested on the target group for comprehension, acceptance, attractiveness, inducement to action and involvement.

Step 7. Interventions

Social mobilization should be part of the overall communication strategy, to encourage participation and thus create a sense of ownership. The community should be mobilized to participate in malaria control, and the necessary services should be prepared to meet the demand created by such activities. Availability of and easy access to effective treatment is the most important sign that the services are ready. Good malaria case management services advertise themselves, i.e. a patient who receives effective treatment from a health facility or community-based health provider, who makes a good clinical recovery and who is well treated in every sense of the term is a better “poster” than printed support materials.

Step 8. Monitoring and evaluation

Indicators of the outcomes and goals set should be used to monitor implementation of a communication strategy. An evaluation to measure the success of interventions against the set objectives should also be undertaken. Examples of communication strategy indicators are:

- whether messages can be remembered;
- number of people trained;
- number of health education sessions conducted;
- numbers of insecticide-treated bednets, rapid diagnostic tests and artemisinin-based combination treatments distributed;
- responses to activities and campaigns;

- actual production and distribution of materials among target groups;
- numbers of radio and television messages aired;
- findings from surveys of behaviour or attitude.

Village-level activities

At village level, activities can be organized by volunteers in collaboration with local administrative personnel and key informants to mobilize people for malaria control. Activities that could be run include:

- establishment of community-based monitoring for malaria prevalence, cases of fever and numbers of people receiving and completing artemisinin-based combination treatments;
- visiting selected families to provide specific information on malaria;
- visiting families at risk for malaria to encourage them to take preventive measures and to seek early diagnosis and treatment when fever develops;
- holding a malaria education session during a village meeting or other event;
- encouraging people to bring bednets for impregnation;
- organizing regular village clean-up days to eliminate mosquito breeding grounds;
- demonstrating proper use of bednets to individual families at risk;
- encouraging village heads of units and women's union representatives to monitor bednet use and persons with symptoms of malaria;
- regularly reminding people to seek medical advice from trained personnel or village health volunteers;
- organizing visits of local health staff to update information on malaria.

9. Monitoring, evaluation and supervision of the malaria control programme

9.1 Sources of information

Most of the information needed to measure the performance of a malaria control programme can be obtained from three sources — routine data, interviews and observations, and surveys — although the quality of the data they provide can vary considerably. Routine data can be collected through the national health information system. This should be the main source of data, because, if a programme has a functioning health management information system, it can be assumed that standardized case registers and reporting forms have been agreed upon and used and the data are of acceptable quality. Health workers can thus use information locally to make rapid decisions. Interviews and observations can be made in health facilities during routine supervisory visits or special surveys. Surveys of specific health facilities and household or community surveys can be carried out.

The first two information sources (routine data, and interviews and observations) should be available to all programmes; surveys will require additional programme resources. Although the cost of conducting surveys might be high, savings can be made by the measurement of several indicators in the same survey. Generally, health facility surveys and household surveys are used to measure indicators for which information is not routinely collected by the health management information system.

For the purposes of monitoring and evaluation, the indicators should be closely linked to the programme's objectives. Since indicators guide health workers in monitoring implementation and progress in order to reorient activities if necessary, the data elements for them should be collected through a routine health management information system. In deciding how many indicators should be used, it should be remembered that accurate measurement of a small number of core indicators is preferable to imprecise measurement of too many. Overburdening of health workers should be avoided, and all information collected should be used. As additional resources become available, and as the programme gains experience, indicators can be refined, improved and expanded.

The epidemiological and operational indicators used to evaluate programme performance are dealt with in greater detail in section 9.3.1 below. A minimum

set of indicators recommended for use in measuring the performance of malaria control programmes is provided in [Annex 3](#).

An indicator can be a number, a proportion, a ratio or a rate. Each health-system level needs indicators according to its reporting requirements and decision-making capacity. Thus, the number and nature of indicators differ according to the health-system level, whether it is the district, subnational, national or global level. A good indicator should be:

- measurable with the available resources;
- valid, i.e. should measure what it is supposed to measure;
- reliable, i.e. the finding is the same when measured by different people under similar circumstances;
- readily interpretable and usable for planning;
- a measure of only one intervention, so that the information can be clearly understood.

To obtain reliable information for planning and monitoring the implementation of the programme and the results achieved, data should be collected on forms. This manual refers mainly to information collected from or through health facilities. As the strengthening of health information systems is a means of strengthening health services, data on the indicators should be collected through the routine health management information system.

Some countries may already have forms to record data in health facilities. The forms described in this section and presented as annexes to this document provide best examples of how information should be collected to ensure that national, regional and global indicators are assessed and used for programme planning and management.

9.2 Monitoring

Monitoring is the act of overseeing the progress of a programme with the aim of ensuring that it achieves the planned objectives. Monitoring is achieved through the collection and analysis of data and providing feedback. Monitoring is therefore a continuous process and is the responsibility of malaria control managers or focal persons at each level. They ensure that the planned activities are being implemented correctly, the data submitted are accurate, complete and valid, and implementation is in compliance with the national malaria treatment guidelines. Broadly, programme implementation and performance can be monitored by analysis of and feedback on routine surveillance data, supervi-

sory visits and feedback, regular, frequent review meetings at all levels and periodic in-depth evaluation.

It is crucial that health workers at local level understand that the information they collect (the forms that they fill in) will be used to improve their own work and the overall health system.

9.3 Programme evaluation

Programme evaluation is necessary to determine the extent to which, at a given time, the planned activities, targets and objectives have been achieved. The targets should be well defined, and epidemiological and operational indicators should be established for measuring them.

9.3.1 Epidemiological and operational indicators

Several indicators are used to evaluate programme performance as a whole and to serve as a basis for the next planning cycle. They should be defined by describing the numerator and the denominator. Epidemiological indicators include, for example, the number of malaria cases treated, by clinical type, age, sex and geographical area; the number of severe malaria cases; and the number of deaths due to malaria.

Operational indicators of planned activities, such as training, logistics, supervision, case management and service delivery, include the proportion or number of health units that have at least one health worker trained in malaria case management, the proportion of health units that can provide a malaria diagnosis by rapid diagnostic tests or microscopy, the proportion of health units that have not had ruptures of medical stocks or other supplies lasting more than one week during the previous three months, and the number of supervisory visits (technical and administrative) undertaken by the district management team or national programme staff during the previous six months.

The malaria health information system should be able to provide reasonably accurate and complete data for most of these indicators by routine data collection on standard forms. Additional information can be gathered from reports of supervisory visits, training records and other forms. Some indicators, however, might require special surveys or studies, on health-seeking behaviour, clinical care, the quality and availability of medicines and other aspects that might not be covered by the routine information system. It is important to use standardized survey methods and protocols in successive surveys to ensure that the data obtained are comparable.

As stated above, Annex 3 (*Malaria case management indicators*) lists some of the operational and epidemiological indicators that can be used for programme evaluation and the sources from which data can be obtained for measuring them. National malaria control programmes should select just a few indicators that can be collected within the available routine health management information system. Indicators should be defined by level of health system, as some indicators are useful only at local level and others at regional or national level. Detailed indicators (for example, by age, sex or place) are more important at local level, where action is to be taken. It is counterproductive to collect information on too many indicators, as this can lead to poor data collection and analysis and can obscure identification of problems.

Below is a recommended minimum set of indicators that can be used by the programme to evaluate its performance in delivering effective malaria case management.

1. Reported annual malaria case rate

Numerator: Total number of malaria cases (uncomplicated and severe)

Denominator: Mid-year resident population x 1000

Notes: Cases can be disaggregated by age or sex. The official United Nations population estimates should be used.

2. Proportion of confirmed malaria cases reported annually

Numerator: Number of malaria cases (uncomplicated and severe) with laboratory confirmation (rapid diagnostic test or microscopy)

Denominator: Total number of malaria cases (uncomplicated and severe, probable and confirmed) x 100

3. Reported death rate from malaria

Numerator: Number of deaths attributed to malaria (probable or confirmed)

Denominator: Mid-year resident population x 100 000

4. Percentage of outpatient malaria cases that received appropriate antimalarial treatment according to national policy

Numerator: Number of outpatient malaria cases receiving antimalarial treatment according to the national drug policy at health facility

Denominator: Number of outpatient malaria cases expected to be treated at health facility level with appropriate treatment x 100.

5. Proportion of patients with diagnosed *P. falciparum* malaria receiving artemisinin-based combination therapies in public health facilities

Numerator: Number of patients with diagnosed *P. falciparum* malaria who received (dispensed at health facility by pharmacy or similar) artemisinin-based combination treatments over a given time

Denominator: Total number of patients with diagnosed *P. falciparum* malaria over the same time x 100

Note: The numerator should be the actual number of patients who received artemisinin-based combination treatments in the health facility after consultation.

6. Proportion of severe malaria cases reported annually

Numerator: Number of severe malaria cases (probable or confirmed) seen at health facilities over a given time

Denominator: Total number of malaria cases (uncomplicated and severe, probable or confirmed) reported by the same health facilities and by the community over the same time x 100

7. Percentage of health facilities reporting no stockout of antimalarial medicines and diagnostics

Numerator: Number of health facilities in areas at risk for malaria reporting no stockouts of first-line antimalarial medicines and RDTs for more than 1 week in a month

Denominator: Total number of health facilities reporting, supervised or surveyed in the same areas at risk for malaria x 100

Note: Information on this indicator is usually obtained during supervisory visits.

8. Proportion of malaria cases treated promptly and appropriately

Numerator: Number of children under 5 years of age and other target groups with fever or malaria (finger or heel prick) during the 2 weeks before the survey who received efficacious antimalarial medicines within 24 hours of onset of fever

Denominator: Total number of children under 5 years of age and other target groups, with fever or malaria (finger or heel prick) during the previous 2 weeks in the population sampled x 100.

Note: Information on this indicator is obtained through surveys.

9.3.2 *Analysing and interpreting the results of evaluation*

Before data are analysed, it is important to ensure that collection was complete and accurate and that the data reflect the actual situation and are representative. Evaluation should include both quantitative indicators and qualitative information collected during technical supervisory visits and routine monitoring. Collected data from all levels of service delivery – community, health unit, district and national levels – should be analysed.

Comparisons should be made between what was planned and what was achieved, comparing indicators with targets, and between health units, districts and regions; in addition, the results of the routine health management information system should be compared with those of previous national surveys. This will help in interpreting variations in programme indicators and in drawing conclusions about trends and whether malaria case management was implemented optimally. The annual report should indicate progress made in achieving the programme targets and should include recommendations about programme elements that should be strengthened or modified in the next planning cycle.

9.3.3 *Improving the health information system*

In order to improve malaria case management and outcomes, the existing health information system must be strengthened. The information provided by the health management information system will indicate how the programme should be improved or reoriented to increase treatment effectiveness and efficiency. Revision could include standardization of recording forms and the introduction of procedures such as a malaria patient card or a malaria registry book at health units. The revision should take into account what needs to be done to improve data collection without overburdening the health worker. Health workers should be trained or retrained in disease classification, treatment regimens, treatment outcomes and in filling in forms.

In certain countries, some of the necessary information is available in two different registers, the general outpatient and the laboratory registers, making it difficult to monitor trends in laboratory diagnosis and treatment given. With the introduction of artemisinin-based combination treatments and the promotion of parasite-based diagnosis (in all patients in low-transmission areas and in older children and adults in high-transmission areas), better documentation is needed to ensure diagnosis and treatment with appropriate medicines. The introduction of a malaria patient card and register at health units could contribute to improved case management in some settings.

The revised case management policies discussed in section 3.2 should form the basis for recording and registering data for monitoring. Existing recording and reporting forms might have to be updated with a change to artemisinin-

based combination treatment in order to cope with new operational targets. When new forms and a malaria patient register are necessary, they should be field-tested before wide use in the health information system. Health workers should be trained in the use of the revised register and in completing recording and reporting forms at the same time as they are trained in the new antimalarial treatment policy and guidelines.

Gradual implementation of the revised information system will allow programme managers to identify and solve any problems while the system is still operating on a small scale. When the new system is introduced in pilot districts, the old system must be continued in the rest of the country in order to maintain the provision of information for monitoring and evaluation. Data from the two information systems must, however, be analysed separately.

Forms are needed for recording and reporting at both health unit and district level. Brief descriptions of and instructions for completing a malaria cases register and recording and reporting forms are given below and in more detail in Annexes 4 to 9.

9.3.4 Recording and reporting forms

Keeping accurate records and reporting periodically on patients and case management activities at all levels of health care are essential for planning the procurement and supplies of medicines and of laboratory and other consumables, for planning staffing requirements and for evaluating programme activities (training, communication for behavioural change, logistics and quality control). All this information can be collected in a patient register and on simple recording and reporting forms (see examples in Annexes 4 to 7).

An effective health management information system requires:

- a malaria patient card for facilitating patient consultation and the filling in of the malaria register at the health unit (see Annex 4, *Malaria patient card*);
- an outpatient and inpatient register (including a simple patient register for community health workers) that is maintained and properly and accurately completed at all health facilities providing treatment for malaria (see Annex 5, *Health unit malaria case register*);
- a laboratory register for recording all cases tested for malaria parasites, with the test results; the laboratory register can be integrated into the outpatient/inpatient register so that a single malaria register is maintained at health facility level (see Annex 5, *Health unit malaria case register*);
- monthly summaries by health facility personnel on the health facility monthly summary report forms of information from the patient register (see Annex 6, *Health unit malaria monthly summary report form*);

- monthly submission of health facility reporting forms to the district level to enable districts to aggregate and summarize information reported from all health facilities on the district malaria monthly summary report form (see Annex 7, *District malaria monthly summary report form*);
- a summary and analysis of monthly data from health facilities by the focal person within the district health management team, who sends a quarterly report to national level using the district malaria monthly summary report form (see Annex 7, *District malaria monthly summary report form*).

Reports of supervisory visits conducted by the district health management team should be used to complement the information sent to national level, especially on staff skills and knowledge and any management issues that might affect malaria control activities.

For efficient functioning of the health management information system, efforts should be made to ensure that useful data for programme planning are collected and analysed at health facilities and districts, with feedback, before transmittal to national level.

Malaria patient card

The intention of a flow card for malaria patients is to help them throughout consultation, diagnosis and treatment and also to help health workers in filling in the malaria register. Many health facilities might not need such a card. It can be used as an outpatient card for recording patient details, clinical assessment, laboratory results, diagnosis, treatment and comments.

The card may be kept by the health facility or taken home by the patient, and should be completed for any patient who is suspected of having malaria. It contains information to be recorded in the health unit malaria cases register: date, name, outpatient department serial number, age, sex, clinical assessment, laboratory results, diagnosis, treatment regimen prescribed, treatment dispensed at health facility (yes or no), and action taken (sent home, referred or admitted) (**Annex 4**).

Health unit malaria case register

Patient registers differ from country to country: some health units keep a general register, while others have a separate one for malaria patients (**Annex 5**). The decision on whether to establish a unique or special register for malaria patients depends on how patients are managed at health facilities and the workload of health workers. It is nevertheless important to ensure that every patient treated for malaria is registered in the health unit.

Health facilities in which malaria patients are managed can keep a register in which all relevant data on patients are recorded. Data on patient cards should

be transferred to the malaria case register at the end of a consultation, after the patient has received a prescription or a drug has been dispensed, to provide complete information for the monitoring and evaluation system. It is a useful record because it facilitates tabulation of data on patients treated at the health unit, it is used as a clinical record and usually cannot be removed from the health unit, it facilitates summaries of relevant information on monthly reporting forms, and, if a patient loses his or her outpatient card, the information can be retrieved from the malaria case register.

The health unit malaria case register form fits on two pages, the left and right sides of a register book. It contains the patient's outpatient serial number at the beginning of each month, full name, age, sex, pregnancy status, address, diagnosis, laboratory confirmation (microscopy, rapid diagnostic test and species), and treatment given and action taken.

Health unit malaria monthly summary report form

The health unit malaria monthly summary report form gives a summary of the information recorded in the malaria patient cases register (or extracted from the health unit register when there is no specific malaria cases register) at the health unit. The summary is used for health unit data analysis and for reporting to the district ([Annex 6](#)). The monthly report provides the information necessary for analysing programme efficiency in malaria case management and variations in disease burden, laboratory diagnosis and treatment outcomes according to selected case management indicators.

District malaria monthly summary report form

The district malaria focal person or officer within the district health management team who is responsible for supervising malaria-control activities compiles and consolidates a report using the information contained in the monthly reports completed by the various health units within a particular district ([Annex 7](#)).

9.4 Supervision

Supervision involves direct observation of how programmes are being performed and the quality of services provided (e.g. patient waiting time, consultation, diagnosis, and treatment dispensed), as a basis for reorienting activities and for conducting on-the-job training when necessary. Good supervision helps managers to identify the weaknesses and strengths of a programme and to initiate corrective measures, and it helps health workers to improve their

efficiency by increasing their knowledge, perfecting their skills, improving their attitude towards work and increasing their motivation. The essential steps in planning a supervisory visit are:

- to determine in advance which activities will be observed and what information will be collected;
- to observe and reinforce the stipulated practices and identify and correct inadequate performance and discrepancies in the various components of malaria case management (diagnosis, treatment, records, stock rupture);
- to identify problems, by supervising the steps followed by patients presenting to a health facility for malaria treatment.

A flow chart of the components of a supervisory visit is shown in **figure 7**.

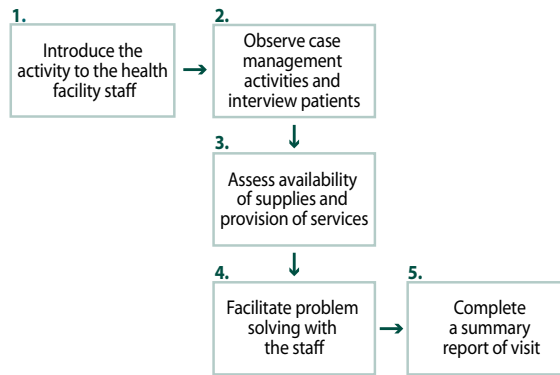


Figure 7 Flow chart of activities during a supervisory visit

At the outpatient department:

- Check the number of recorded malaria cases seen and referred to the laboratory for blood slides or rapid diagnostic tests.
- Check the number of recorded malaria cases that were confirmed by microscopy or rapid diagnostic tests.
- Check how many patients were prescribed artemisinin-based combination treatments and how many actually received them (dispensed) at the health facility.
- Check the system in place for quality control of microscopy and the performance of rapid diagnostic tests.
- Check the time between taking blood and receiving the results of blood slides or rapid diagnostic tests.

- Examine the positivity rate among persons examined for malaria.
- Check for consistency between laboratory results and information entered into the health unit malaria outpatient cases register.

Other activities:

- Check whether health workers and other key staff are in place and whether they have been trained.
- Check the availability and expiry dates of essential medicines and supplies: first- and second-line artemisinin-based combination treatments, parenteral quinine or artesunate, syringes and needles, water for injection, slides, rapid diagnostic tests and others.
- Check the availability of malaria patient cards, a malaria case register, laboratory forms, stock record forms, referral forms, admission charts, tally sheets and monthly reporting forms.
- Check that material for communication for behavioural change is visibly displayed in the facility and that health education sessions are being conducted in the outpatient department.
- Check that patients attending the outpatient department are informed about malaria prevention and treatment.

Examples of comprehensive *checklists for malaria case management supervision* are provided in Annex 8. They consist of checklist forms for the assessment of trained health worker performance, for discharge interviews with the patient or the patient's caregiver and for the assessment of health unit support and activities. These forms help the supervisory team to supervise, provide feedback, solve problems and make a comprehensive report. Supervision must be conducted regularly, with the support of clinical staff, to help health workers and conduct training. To ensure high-quality supervision, a district health management team should therefore include clinicians working in hospitals or other health institutions. Supervisory visits should be conducted quarterly and the reports sent to the district level for analysis.

9.5 Surveillance of resistance to antimalarial drugs

Resistance to antimalarial drugs has emerged as a leading threat to malaria control efforts. As resistance to one or more antimalarial drugs develops, malaria control programmes must be able to evaluate the efficacy of the drugs in use and provide timely, relevant, reliable and understandable information.

Data from drug efficacy studies are essential, not only for maintaining confidence that the current treatment recommendations are adequate in relation to malaria patients' needs, but also, should that not be the case, for generating convincing evidence that the current treatment recommendations should be changed. When such evaluations are conducted consistently over time in a reasonable and representative selection of sites, programmes should be able to provide information that will allow changes in treatment recommendations or policies to be made early enough to minimize the impact of a failing treatment regimen. WHO has developed standardized protocols³ for monitoring drug efficacy, and malaria control programmes are encouraged to conduct efficacy studies according to these protocols.

Guidance on reviewing and changing the national antimalarial treatment policy and on implementing a new treatment policy is provided in section 10.

10. Reviewing and changing the antimalarial treatment policy

10.1 *Deciding to change the treatment policy*

Changing the national antimalarial treatment policy requires concerted action among all stakeholders and continuous stewardship by the ministry of health. Consensus must be reached on the new treatment policy before it is implemented.

The key evidence for deciding to change treatment policy is failing therapeutic efficacy of the antimalarial drugs in use, assessed according to standard WHO protocols. The current WHO recommendation is that the policy should be changed if the rate of treatment failure exceeds 10% on day 28. Therapeutic efficacy is being assessed at sentinel sites in countries, through country and inter-country networks. Other factors that influence a decision to change treatment policy include consumer and provider dissatisfaction and increasing malaria morbidity and mortality.

³ Assessment and monitoring of antimalarial drug efficacy for the treatment of uncomplicated falciparum malaria. Geneva, World Health Organization, 2003 (WHO/HTM/RBM/2003.50).

Once adequate evidence has become available, the ministry of health coordinates the process of consensus building among stakeholders through negotiations and meetings. This culminates in a technical review meeting, leading to a policy recommendation to the ministry.

10.2 Implementing a new treatment policy

Once the ministry of health has adopted a new treatment policy, a multisectoral steering committee should be appointed to guide its implementation. The process involves resource mobilization, updating of national treatment guidelines, and training of health workers, review of drug procurement plans, strengthening drug supply systems, formulating delivery strategies, communicating to the public and monitoring and evaluation. All stakeholders participate in implementation according to their expertise and comparative advantages, working through the steering committee or its working groups. Critical areas and actions required for effective implementation of policy are:

1. Framework for implementation

- general framework for implementing policy
- implementation objectives
- operational strategies to meet the objectives
- deployment strategy (countrywide or phased)
- strategy to ensure laboratory support
- framework for community mobilization and deployment

2. Procurement and distribution of supplies

- estimation of needs (medicines and diagnostics)
- sourcing and procurement
- drug distribution system and mechanisms

3. Quality assurance

- quality of supplies (medicines and diagnostics)
- quality of patient care

4. Orientation of health workers

- training
- supervision

5. Communication and social mobilization

- information strategy for advocacy
- strategy to enhance compliance with treatment
- mobilization of the community for social responsibility in malaria control

6. Regulatory and registration control

- regulatory issues for current antimalarial agents such as chloroquine and sulfadoxine-pyrimethamine
- registration and regulation of new antimalarial agents (artemisinin-based combination treatments)
- fate of other monotherapies
- withdrawal of marketing authorization for artemisinin and associated monotherapies

7. Resource mobilization and financing

- estimation of resources needs (financial and human)
- estimation of financial requirements (procurement and process needs)
- identification of resource gaps
- identification of resource sources (e.g. partners)

8. Monitoring and evaluation

- policy implementation
- adherence of health care providers and consumers to the new policy
- therapeutic efficacy
- pharmacovigilance.

9. Work plan

- Log of specific activities with specific time lines and implementation targets:

ACTIVITY	Cost	Time frame	Responsible person	Institution
1. Constitute body to oversee implementation				
2. Write or update national policy document				
3. Write or update national treatment guidelines				
4. Write or update case management training manuals				
5. Orient medical doctors to new policy				
6. Orient nurses to new policy				
7. Orient community health agents to new policy				
8. Develop and disseminate communication materials on new policy				

Changing a malaria treatment policy requires the mobilization of significant resources and concerted action among stakeholders at country level. For these reasons, policy change is increasingly used to expand access to effective drugs at all levels. This involves in particular:

- strengthening drug registration and regulation for deployment of new, effective drugs at various levels of the health system (public, private, formal and informal);
- drawing up policies to enable the private health sector to provide effective treatment with high-quality drugs and price regulation to improve affordability;
- improving systems for forecasting drug needs, as the cost of the new ACTs is at least 10 times higher than the cost of the failing monotherapeutic antimalarial drugs used previously;
- strengthening the management and drug supply system (procurement, distribution and use) according to the specificities of the new drug(s) (shorter shelf-life and course-of-therapy packs);
- training health workers in both public and private sectors, including drug vendors;
- communicating behavioural change to consumers and providers;
- strengthening the programme's capacity for monitoring and evaluation, in particular for investigating drug use and treatment-seeking behaviour and pharmacovigilance;
- assessing the therapeutic efficacy of the new drug(s);
- conducting operational research on use of rapid diagnostic tests;
- providing combination therapy near the home.

The time needed to improve access to effective treatment at country level will be shortened by early planning of the events that will lead to updating and implementing an effective antimalarial treatment policy.

11. Pharmacovigilance

Monitoring the safety of all drugs is a necessity for public health. After the introduction of new antimalarial drug combinations, such as artemisinin-based combination treatments, appropriate pharmacovigilance systems are needed to monitor the occurrence of unexpected adverse reactions (the nature or severity of which is not consistent with domestic labelling or market authorization or expected from the characteristics of the drug). A generic system is proposed to identify adverse events associated with all drugs, including those for malaria.

The objectives of a pharmacovigilance system are:

- to detect “signals” of adverse drug reactions (a response to a medicine which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function) after the introduction of a new drug or drug combination;
- to assess signals to evaluate causality, clinical relevance, frequency and distribution in particular population groups;
- to communicate and make recommendations to authorities and the public;
- to make appropriate responses and take appropriate action in terms of drug registration, drug use or training and education of health professionals and the public; and
- to monitor the outcome of the responses or actions taken (e.g. reduction in risk for a specific sign, improved drug use or improved outcome of patients experiencing a detected adverse reaction).

A reportable serious adverse event requires, at a minimum, an identifiable source of information or reporter; an identifiable patient, suspected product(s) and suspected reaction(s).

The reporting system should extend only to the clinic and dispensary level of the health care system, as the persons reporting adverse events or experiences must be literate, since the system depends on written records on a standard adverse event report form. A model *serious adverse events report form* and a *checklist for investigation of serious adverse events* are shown in **Annex 9**.

While pharmacovigilance is conducted only within the formal health service (including private clinics), awareness of its importance in the informal sector is considered essential, particularly among community leaders, shopkeepers, traditional healers and community health workers, as well as religious leaders and schoolteachers. Informal health care providers can play an important role in referring patients to health facilities if adverse events occur.

In addition to trained health professionals for reporting serious adverse events correctly and an informed public, an investigation team is needed at the district hospital. This team is essential for validating case reports from the entire district and for communicating with an expert safety review panel at national level. This panel, consisting of a clinical pharmacologist, a physician, an obstetrician, a paediatrician and a pharmacist, should meet regularly to review aggregated case reports validated by the district investigation teams and to advise on what action should be taken.

The responsibility for communicating with the public, the media, health care providers and the national health authorities lies with the national coordinator who oversees the pharmacovigilance system. The person in this full-time position coordinates communication, training and supervision of the district investigation teams and acts as the secretariat for the national expert safety review panel. He or she is responsible for collecting and storing all reports of adverse events and coordinating communications with the drug regulatory authority, the ministry of health, the Uppsala Monitoring Centre (which is a WHO Collaborating Centre for International Drug Monitoring) and WHO.

Less serious adverse drug reactions, such as nausea, vomiting or diarrhoea, are not investigated further, but suspected serious adverse events (any untoward medical occurrence that at any dose results in death, is life threatening, requires or prolongs patient hospitalization, results in persistent disability or incapacity or is a congenital anomaly or birth defect, as defined by the International Conference on Harmonization) should be investigated promptly and completely. The District Investigation Team (DIT) should verify and complete the adverse events report form and ensure that cases are investigated fully, by gathering information from the patient, relatives, health workers, supervisors and community members.

An assessment should be made about the causality of the relation between the suspect serious adverse reaction and the medicine, expressed in levels of probability (very likely or certain, probable, possible, unlikely, unrelated or unclassifiable). The expert safety review panel confirms the assessment of causality made by the DIT, determines the rate of reported serious adverse events on the basis of estimated drug use and compares the rates associated with different antimalarial medicines to make recommendations to the ministry of health.

11.1 Questions to ask in assessing causality

- What was the precise nature of the reaction?
- Did the reaction occur within a reasonable time after start of treatment with the suspected drug?
- Is the reaction known to occur with the particular drug, as stated on the package insert or other reference?
- Did the patient recover once the medication was stopped?
- Did the patient take the medication again after the reaction had occurred (i.e. rechallenge)? If so, did the same reaction occur?
- Can this reaction be explained by other causes (e.g. underlying disease, other drugs, toxins or foods)?

12. Integration of malaria case management into other health programmes

Malaria case management is usually part of overall clinical service delivery in a country, most activities taking place at district level and at health institutions in both the public and the private sector. Thus, most activities in case management should be conducted at all levels and not be implemented as independent programmes.

At the level of the national malaria control programme, case management should be integrated into all stages of the national malaria control strategy, from planning to resource mobilization, strategy development, capacity building and implementation. The national malaria control programme should ensure adequate collaboration and dialogue with other health programmes and departments, including clinical services, maternal and child health services, pharmacy, national drug regulatory authorities, health education, central medical stores and laboratory services. The integration of malaria case manage-

ment into other health programmes can reduce duplication, thus saving costs and time and ensuring consistent methods and messages.

One example of integration would be to use existing structures and strategies for maternal and child health services, such as the Integrated Management of Childhood Illness strategy, for the training of health workers, supervision, provision of clinical services as well as for counselling and health education. National regulatory authorities could support the programme by ensuring the quality of medicines and pharmacovigilance and regulating the availability and rational use of appropriate medication in the country. Central medical stores can provide support in the form of quantification, procurement, distribution and supply of antimalarial medicines and diagnostic supplies.

Health education units can ensure that communication for behavioural change with regard to malaria treatment and health-seeking behaviour is integrated into the national communication strategy, including the formal education sector (e.g. primary and secondary schools, medical schools, nursing schools, schools of public health, and adult education programmes) and other sectoral programmes (e.g. agriculture and microcredit schemes). This could be achieved by extending the curricula to include content relevant to malaria case management, joint development and production of supporting materials, introducing more participatory tools into schools, pre-service training and follow-up, and in-service training. A mix of interpersonal and mass media methods is most effective in capturing attention and obtaining high-level political commitment to and involvement with the community.

13. Working with the private sector

In many countries where malaria is endemic, the number and distribution of public and formal sector health facilities are frequently insufficient to reach many populations at risk. Private commercial and informal medicine sellers are therefore a major source of health care, and use of their services for malaria treatment can range from 15% to 82%, depending on the country. They are, however, diverse and usually operate informally in an unregulated environment, often delivering poor-quality service. Interventions are therefore needed

to improve access to high-quality, appropriate, and effective antimalarial medicines as part of malaria control activities outside the formal public sector.

The role of private providers depends on the local situation, the characteristics of the providers and their approaches; collaboration with them therefore varies greatly. The information provided here might not be applicable in all settings but gives guidance to working with the private sector in malaria case management. This should be undertaken primarily by the national malaria control programme, with the initial involvement of stakeholders in public, private and nongovernmental organization sectors. The national programme must determine at the outset a policy on the use of artemisinin-based combination treatments and other antimalarial medicines by private providers, but should remain open to changes in its approach with increasing experience.

Although formal and informal private practitioners contribute extensively to malaria treatment, few specific interventions have been made to improve the quality of their services. The guiding principles are based on observations of the roles that the private sector plays in the diagnosis and treatment of malaria in a number of countries. Understanding the contribution of this sector to malaria treatment requires analysis of the issues involved in changing to artemisinin-based combination treatments, which have implications for their use by private providers. The issues include drug supply and regulation and decisions about who should be allowed to dispense or sell the new treatments in order to ensure rational use, improved diagnosis, cost containment, behavioural change and adherence to national treatment guidelines.

13.1 Drug regulatory issues

A legal framework must be set up for private providers, especially informal providers, to ensure equity and to improve access to high-quality, appropriate and effective treatment. The national malaria control programme should take direct responsibility for drawing up and implementing standard treatment guidelines, which should be communicated to the national regulatory authorities to ensure that regulations for national treatment formularies and drug importation correspond to national policies. The regulatory authorities should also ensure that drugs imported into or manufactured in the country meet drug production standards according to good manufacturing practice.

The national regulatory authorities should try to limit registration of antimalarial agents that are not included in the national malaria treatment guidelines. The national formulary should be updated to contain information only on approved antimalarial agents.

13.2 Training and supervision of formal private providers

The strategic options for improving malaria case management in the public sector are equally relevant to formal private sector providers. In most cases, the same personnel operate in both sectors interchangeably, so that efforts to improve the quality of care in the public sector will extend to the private sector. Private providers should be included in a national implementation plan for new treatment policies and monitoring and supervision. This can be done through professional associations and planned to fit in with their work schedules. Training and supervision should be conducted to improve the skills of providers in diagnosis, treatment, the reporting of adverse events, and communication.

Some countries have addressed the role of formal and informal private sector providers, including private pharmacists and some informal drug sellers, by providing incentives, such as peer accreditation, government loans or microfinance systems for improving premises, working with and supporting private providers' organizations and franchising. In some situations, the number and distribution of providers who can deliver recommended treatments may be expanded by including those already providing care in the informal sector. In other situations, it might be necessary to create new groups of providers or train those doing other community health work to take on malaria case management.

Strategies to reduce the inappropriate use of antimalarial drugs include improving diagnosis and targeting high-risk populations. Private providers should be trained in the new treatment policy and given clear guidelines and dosage charts to reduce the inappropriate use of antimalarial drugs. These measures, and ensuring compliance with regulations, might limit the use of monotherapeutic antimalarial drugs and poor-quality or counterfeit artemisinin-based combination treatments.

13.3 Communication for behavioural change

The behaviour of private providers can also be influenced by information, education and communication activities and by improving access to knowledge about recommended medicines and correct dosing regimes. This knowledge empowers communities, which can then demand the appropriate recommended treatment. It is also important to create social responsibility among private providers so that they provide high-quality, approved artemisinin-based combination treatments only after parasitological confirmation.

13.4 Availability and marketing of drugs

The phased introduction of artemisinin-based combination treatments, initially in the public sector, then in the formal private sector and finally in the informal private sector, might be the most practical approach. The fact that the new combination treatments are for sale in only a few pharmacies and clinics should be considered, and a plan should be developed for their introduction into the private sector with removal of the current monotherapies. The malaria control programme should work closely with drug regulatory agencies and industry to ensure that the marketing strategies used are consistent with the national policy and recommendations. National regulatory authorities should ensure that only drugs recommended in the national treatment guidelines are promoted and marketed by the private sector through the media and advertisements.

Drug regulatory authorities and nongovernmental organizations could select private providers, train them in the use of the antimalarial medicines recommended in the malaria treatment guidelines and follow up their compliance. Compliant private providers could then attain certification. Information should be provided to the public to raise their awareness about drug quality and to improve compliance with treatment with “the right” antimalarial drugs.

A major practical issue to be addressed is making highly subsidized treatments available through the private sector. In many countries, some artemisinin-based combination treatments are already registered and are therefore available through the private sector, like the monotherapies. Private providers who prescribe the monotherapies should be encouraged to prescribe the recommended artemisinin-based combination treatments instead.

13.5 Challenges for private providers

The involvement of informal providers will increase access to artemisinin-based combination treatments in areas where the formal health system is inadequate. It will minimize the use of monotherapies by making high-quality artemisinin-based combination treatment available in all outlets. Such involvement will also limit the marketing of substandard and counterfeit antimalarial agents by reducing the incentives for obtaining drugs illegally from the formal sector or purchasing counterfeits to meet demand.

As artemisinin-based combination treatments will inevitably become available to formal and informal providers, with major risks and benefits, strategies

must be mounted to manage the risks effectively. The main risks associated with increased access to these drugs by medicine sellers in the informal private sector include:

- overuse in the absence of a diagnosis, especially by adults;
- misuse, as retailers might give wrong dosages;
- splitting blister packs into component monotherapies (when they are not co-formulated);
- delaying attendance by patients with severe malaria for qualified health worker evaluation, thus increasing the risk for severe complications and death;
- misuse of subsidies, which would divert funds from potentially more cost-effective interventions;
- inequitable access if treatment is not subsidized.

The national malaria control programme should not recommend different antimalarial medicines for the public and private sector, in order to avoid sending complex messages.

ANNEX 1

Health unit monthly stock management form for medicines and laboratory supplies

The purpose of the monthly stock management form for medicines and laboratory supplies is for monitoring of medicine consumption and stock rupture. Consumption is presented in a standard way, as treatment units (packs) by age-dosage category depending on the type of antimalarial medicine used in the country.

Explanatory notes

The following explanatory notes for completing the health unit monthly stock management form relate to the model form shown in Appendix 1. The form is divided into four columns, which are explained below.

1. *Item*

In this first, or stub, column, indicate by writing the names of the antimalarial medicines being used as first-line, second-line and for severe malaria treatment; include all other medicines, rapid diagnostic tests, laboratory supplies and any other essential supplies that you would like to monitor.

2. *Duration of stock-out*

Tick as appropriate, depending on whether there was any stock rupture during the month or period being reported on. Tick “None” for items for which there was no stock rupture; “< 1 week” for items for which there was stock rupture for less than one week, and “> 1 week” for items for which there was a stock rupture of more than one week.

3. *Stock management (treatment courses)*

This section helps in the management of antimalarial medicine stocks, so that the health unit can quantify the correct amounts of medicines and supplies required to avoid stock rupture or over-stocking.

- 3a. **Safety stock:** quantity of stock held to satisfy unexpectedly high requirements in the period, which should always be kept in stock in the health facility to ensure an uninterrupted supply.
- 3b. **Opening stock (stock at beginning of month):** total number of treatment courses of first-line antimalarial medicines for each presentation and all other antimalarial agents and other supplies at the health facility at the beginning of the month.
- 3c. **Closing stock (balance at end of month):** total amount of antimalarial medicines in stock at the health facility at the end of the month.
- 3d. **Monthly consumption:** total number of treatment courses dispensed per presentation of first-line, second-line and severe malaria treatment or rapid diagnostic tests and any other supplies.

- 3e. **Expected variation:** anticipated number of antimalarial treatment courses over or below the usual consumption, depending on the anticipated increase or reduction in needs over the next month. This can depend on seasonality (e.g. rain just after season with expected increase; dry season with expected decrease) or active case detection. The expected variation should be expressed as a multiplication factor; for example, 1 = no expected variation in requirements; 0.5 = expected reduction by 50%; and 1.5 = expected increase by 50%.
- 3f. **Lead time:** time between placing an order and receiving medicines or supplies, expressed in months; e.g. 0.5 if it takes two weeks; 1 if it takes one month; 2 if it takes two months.

4. Quantity re-ordered

It is the total number of treatment courses of antimalarial medicines or other supplies actually re-ordered.

The recording form makes it possible to monitor monthly consumption and the real-time requirements for re-supply of medicines to health facilities. It also makes it possible to evaluate safety stocks at health facility level and expected variations in estimated amounts of malaria medicines and supplies to be re-ordered.

The information collected makes it possible to calculate the amounts of medicines and supplies delivered in the same month to the same health unit, by comparing the actual closing stock (3c) with the difference between the opening stock (3b) and consumption (3d), using the formula provided under section 5.1.2:

$$\text{medicines delivered} = \text{monthly consumption (3d)} + \text{closing stock (3c)} - \text{opening stock (3b)}$$

The information collected may also make it possible to compare the adequacy of re-order levels, by comparing the actual quantities re-ordered (3f) with the theoretical amount, which can be calculated from the formula provided under 5.2.3:

$$(3d \times 3e \times 3f) + 3a - 3c = \text{quantity of medicines to be re-ordered}$$

where:

$$3a = \text{safety stock}$$

The officer in charge of the health unit should check for consistency and completeness before submitting the report to the district malaria officer or the malaria focal person.

Appendix 1

Model monthly stock management form for medicines and laboratory supplies

District Health unit Month

Item	Duration of stock-out		Stock management (treatment courses)				Quantity re-ordered		
	None	< 1 week	> 1 week	Safety stock	Opening stock	Closing stock		Monthly consumption	Expected variation
Name of first-line medicine									
1. ACT Prepack 1									
2. ACT Prepack 2									
3. ACT Prepack 3									
4. ACT Prepack 4									
5. Second-line medicine									
6. Parenteral quinine									
7. Artemisinin suppositories									
8. Sulfadoxine-pyrimethamine for IPT									
Additional medicines or supplies:									
9.									
10.									
Laboratory supplies:									
11. Giemsa stain									
12. Malaria slides									
13. RDTs									
14. Lancets									

Opening stock: stock at beginning of month; closing stock: balance at end of month

ACT = artemisinin-based combination therapy; IPT = intermittent preventive treatment; RDT = rapid diagnostic test.

ANNEX 2**Model checklist for malaria laboratory supervision**

1. Month 2. Year 3. Code

4. Name of unit 5. Location

6. Personnel

	Names of personnel	Post description	Date of service
6a			
6b			
6c			
6d			
6e			

7. Assessment of blood slide quality Thick film Thin film

8. Assessment of blood slide staining Quantity Quality

9. Assessment of blood slides examined

Total examined	Positive	Pf	Pv	Pm	Po	Pmix

10. Assessment of diagnostic microscopes

Microscope No.	Ocular	Prism	Oilimmersion	Condenser	Mechanics	Illuminator	Blue filter
10a							
10b							
10c							

11. Assessment of microscope diagnosis

Name of microscopist	Exam	Pos.	Neg.	Pf	Pv	Pm	Po	Pmix
11a								
11b								
11c								
11d								

12. Assessment of record-keeping and other related activities

Comments:

13. Space for additional comments (please specify respective section):

14. Prepared by: 15. Date

Pf = *Plasmodium falciparum*; Pv = *Plasmodium vivax*; Pm = *Plasmodium malariae*; Po = *Plasmodium ovale*; Pmix = mixed *Plasmodium falciparum* and *Plasmodium vivax*; Pos. = positive; Neg. = negative

Appendix 1

Instructions for completing the checklist for malaria laboratory supervision

- Box 1 Month of quality control evaluation visits
- Box 2 Year of quality control evaluation visits
- Box 3 Identification code of quality control evaluation report (if any)
- Box 4 Name of health unit being evaluated
- Box 5 Location of health unit being evaluated
- Box 6 Names of personnel employed in the preparation, processing, staining, examining, recording or reporting of blood slides in the health unit. Post descriptions of health unit workers (e.g. microscopist). Date on which the staff member was recruited and trained.
- Box 7 Assessment of a sample of blood slides examined during the period to ascertain the quality of the preparation of thick and thin films
- Box 8 Examination of a sample of blood slides stained during the period to ascertain:
 - 1. the quality of staining of thick and thin films;
 - 2. the total quantity of blood slides stained.
- Box 9 Analysis of blood slide examination results, giving:
 - 1. the total number of blood slides examined;
 - 2. the total number of blood slides positive for each of the four Plasmodium species and mixed-species malaria infections.
- Box 10 Assessment of the operational efficiency of the microscopes in use at the health unit. A unique identification number should identify each microscope. (Usually, each microscope is assigned to a specified individual, and this practice should be encouraged.) Each of the listed elements (e.g. prism) should be physically checked and its condition noted. Appropriate remedial action should be initiated as required. The supervisor should always carry replacement parts (such as spare lenses) in order that minor repairs can be made on site.
- Box 11 Assessment of individual microscopist's diagnostic output, showing:
 - 1. the total number of blood slides examined;
 - 2. the total number of slides positive for each of the four Plasmodium species and mixed-species malaria infections.
- Box 12 Assessment of record-keeping at the health unit to ensure that the records are correct and up to date. Analysis of the health unit records can highlight the strengths and weaknesses of staff and indicate where remedial or refresher training is required.
- Box 13 Space for further information about the health unit's activities as they relate to quality control in malaria diagnosis
- Box 14 Signature of person conducting the quality control evaluation visit
- Box 15 Date of quality control evaluation visit

ANNEX 3

Malaria case management indicators

I. Indicator **Reported annual malaria case rate**

Calculation	<p>Numerator: Number of malaria cases (probable or confirmed) reported by health facilities over a given time (age groups and sex could be used, depending on local epidemiology)</p> <p>Denominator: Mid-year resident population x 1000</p>		
Definitions of key terms	<p>A malaria case is a clinical episode of illness, defined as:</p> <ul style="list-style-type: none"> • <i>Uncomplicated malaria</i>: fever or recent history of fever with or without other signs or symptoms of severe malaria^{1,2} • <i>Severe malaria</i>: requires hospitalization with signs or symptoms of severe malaria^{1,3} • <i>Probable malaria</i>: signs or symptoms of malaria but without parasitological confirmation, receiving antimalarial treatment^{1,4,5} • <i>Confirmed malaria</i>: signs or symptoms of malaria, receiving antimalarial treatment and laboratory confirmation of diagnosis³ <p>Health facilities: public (government or owned by local administration) or private (non-profit or for-profit organizations)</p> <p>Community case: reported by community health workers, administrators and other personnel operating at village and community levels</p> <p>Disaggregated analysis by (i) confirmed case and (ii) age: <5 years and all ages</p> <p>Reporting completeness: percentage of health facilities reporting data within a nationally established time frame out of the total existing facilities expected to report</p> <p>Population: official United Nations population estimates</p>		
Purpose	To contribute to measuring the impact of interventions using trend analysis of morbidity and the burden of disease; a proxy of incidence rate in a defined area and during a defined period		
Data collection			
<i>Method</i>	<i>Tools</i>	<i>Level</i>	<i>Frequency</i>
Health management information service: routine or integrated disease surveillance or malaria surveillance. Absolute numbers for numerator and denominator and reporting completeness must be reported with the rate	Registers from outpatient and inpatient departments; confirmed cases from outpatient registers or laboratory registers; community health forms	District, province, region, country	Annually (at global level)
Interpretation and use	The indicator allows comparison of malaria burden between area within country as well as among countries, and supports planning, stratification, allocation of resources and targeting interventions. The number of malaria cases is influenced by multiple factors, some directly related to malaria control (case management and vector control) and intensity of malaria transmission in the area, others related to access to health services, completeness of health facility reporting, diagnostic capacity and under-notification of cases due to self-treatment.		
References	<ol style="list-style-type: none"> 1. WHO Expert Committee on Malaria. Twentieth report. Geneva, World Health Organization, 2000 (WHO Technical Report Series, No. 892), pp. 46–47; 2. Guidelines for the treatment of malaria. Geneva, World Health Organization, 2006, pp. 5–8. 3. Guidelines for the treatment of malaria. Geneva, World Health Organization, 2006, p. 41. 4. Framework for monitoring progress and evaluating outcomes and impact. Geneva, World Health Organization/Roll Back Malaria, 2000 (WHO/CDS/RBM/2000.25), pp. 10–13; 5. World malaria report 2005. Geneva, Roll Back Malaria/World Health Organization/UNICEF 2005 (WHO/HTM/MAL/2005.1102), pp. 75–84, Table 13, p. 291. 		

2. Indicator **Proportion of confirmed malaria cases reported annually**

Calculation	<p>Numerator: Number of malaria cases (uncomplicated and severe) with laboratory confirmation (rapid diagnostic test or microscopy), reported by health facilities and by community-level health workers over a given time</p> <p>Denominator: Total number of malaria cases (uncomplicated and severe, probable and confirmed), reported by health facilities and by communities over a given time x 100</p>		
Definitions of key terms	<p>Health facilities: public (government or owned by local administration) or private (non-profit and for-profit organizations)</p> <p>Community case: malaria cases reported by community health workers, administrators and other personnel operating at village and community levels</p> <p>Disaggregated analysis by age: <5 years and all ages</p> <p>Reporting completeness: percentage of health facilities reporting data within a national established time frame out of the total existing facilities expected to report</p>		
Purpose	To measure the proportion of cases that are treated based on parasite confirmation to minimize misdiagnosis.		
Data collection			
<i>Method</i>	<i>Tools</i>	<i>Level</i>	<i>Frequency</i>
Health management information service: routine or integrated disease surveillance or malaria surveillance. Absolute numbers for numerator and denominator and reporting completeness must be reported together with the rate	Health facility records, registers and community health forms	District, province, region, country	Annually (at global level)
Interpretation and use	This proportion indicates true malaria cases resulting from improved quality of services and efficiency. Both programme implementation and health system capacity influence these achievements. In high transmission areas, many <5 children are treated on the basis of clinical diagnosis alone. However, with decreasing malaria burden, diagnosis will be required for all ages. Age-disaggregated data could be provided.		
Reference	<i>Framework for monitoring progress and evaluating outcomes and impact.</i> Geneva, World Health Organization/Roll Back Malaria, 2000 (WHO/CDS/RBM/2000.25), pp. 10–13.		

3. Indicator **Reported death rate from malaria**

Calculation	<p>Numerator: Number of deaths attributed to malaria (probable or confirmed) reported by health facilities over a given time</p> <p>Denominator: Mid-year resident population x 100 000</p>			
Definitions of key terms	<p>Deaths attributed to malaria include:</p> <ul style="list-style-type: none"> • Probable death from malaria: death of a person in whom probable severe malaria was diagnosed¹ • Confirmed death from malaria: death of a person in whom severe malaria was diagnosed, with laboratory confirmation of diagnosis¹ <p>Health facilities: public (government or owned by local administration) or private (non-profit and for-profit organizations)</p> <p>Reporting completeness: percentage of health facilities reporting data within a nationally established time frame out of the total existing facilities expected to report</p>			
Purpose	To measure trends in mortality and burden of disease			
Data collection				
<i>Method</i>	<i>Tools</i>	<i>Level</i>	<i>Frequency</i>	
<p>1. Health management information service: routine or integrated disease surveillance or malaria surveillance</p> <p>2. Civil registration</p> <p>From both sources, absolute numbers for numerator and denominator and reporting completeness must be reported with the rate.</p>	<p>1. Health facility records and registers</p> <p>2. Death certificates</p>	<p>District, province, region, country</p>	<p>Annually (at global level)</p>	
Interpretation and use	<p>The indicator allows comparison of malaria burdens between different parts of a country and among countries, and supports planning and allocation of resources. To a greater extent than for malaria cases, the number of deaths is subject to multiple factors, some directly related to malaria control and the intensity of malaria transmission in the area, others related to access to health services, health facility reporting completeness, diagnostic capacity and under-notification of people dying at home.</p>			
References	<p>1. <i>WHO Expert Committee on Malaria. Twentieth report.</i> Geneva, World Health Organization, 2000, pp. 46–47</p> <p>2. <i>Framework for monitoring progress and evaluating outcomes and impact.</i> Geneva, World Health Organization/Roll Back Malaria, 2000 (WHO/CDS/RBM/2000.25), pp. 10–13</p> <p>3. <i>World malaria report 2005.</i> Geneva, Roll Back Malaria/World Health Organization/UNICEF 2005, pp. 75–84, Table 13, p. 291.</p>			

4. Indicator **Percentage of outpatient malaria cases that received appropriate antimalarial treatment according to national policy**

Calculation	<p>Numerator: Number of outpatient malaria cases receiving antimalarial treatment according to the national drug policy at health facility</p> <p>Denominator: Number of outpatient malaria cases expected to be treated at health facility level with appropriate treatment x 100</p> <p>Both in numerator and denominator, disaggregation of treatment for <i>P. falciparum</i> and <i>P. vivax</i> based on national policy is required.</p> <p>If number of outpatient cases treated is not available, then number of treatment courses dispensed or delivered can be used as surrogate numerator.</p>		
Definitions of key terms	<p>Health facilities: mainly public (government or owned by local administration) or private, non-profit organizations</p> <p>Reporting completeness: percentage of health facilities reporting data within a nationally established time frame out of the total existing facilities expected to report</p>		
Purpose	To monitor coverage with access to effective antimalarial treatment according to national policy. It also helps programmes to estimate better the needs of 1st-line antimalarial medicines		
Data collection			
<i>Method</i>	<i>Tools</i>	<i>Level</i>	<i>Frequency</i>
Health management information service: routine. Absolute numbers for numerator and denominator and reporting completeness must be reported with the rate.	Health facility records and registers	District, province, region, country	Annually (at global level)
Interpretation and use	The indicator measures access to artemisinin-based combination treatments at health facility level in the management of <i>P. falciparum</i> malaria. This is a transient indicator, as countries that have fully introduced artemisinin-based combination therapies countrywide may not need it.		

5. Indicator *Proportion of patients with diagnosed *P. falciparum* malaria receiving artemisinin-based combination therapies in public health facilities*

Calculation	<p>Numerator: Number of patients with diagnosed <i>P. falciparum</i> malaria who received (dispensed at health facility by pharmacy or similar) artemisinin-based combination treatments over a given time</p> <p>Denominator: Total number of patients with diagnosed <i>P. falciparum</i> malaria over the same time x 100</p>			
Definitions of key terms	<p>Health facilities: mainly public (government or owned by local administration)</p> <p>Reporting completeness: percentage of health facilities reporting data within a nationally established time frame out of the total existing facilities expected to report</p>			
Purpose	To monitor coverage with artemisinin-based combination treatments. This indicator should be used if indicator number 4 (with disaggregation of treatment given and cases on the basis of malaria species) is not available			
Data collection				
<i>Method</i>	<i>Tools</i>	<i>Level</i>	<i>Frequency</i>	
Health management information service: routine. Absolute numbers for numerator and denominator and reporting completeness must be reported with the rate.	Health facility records and registers	District, province, region, country	Annually (at global level)	
Interpretation and use	The indicator measures access to artemisinin-based combination treatments at health facility level in the management of <i>P. falciparum</i> malaria. This is a transient indicator, as countries that have fully introduced artemisinin-based combination therapies countrywide may not need it.			

6. Indicator **Proportion of severe malaria cases reported annually**

Calculation	<p>Numerator: Number of severe malaria cases (probable or confirmed) seen at health facilities over a given time</p> <p>Denominator: Total number of malaria cases (uncomplicated and severe, probable or confirmed) reported by the same health facilities and by the community over the same time x 100</p>			
Definitions of key terms	<p>Health facilities: public (government or owned by local administration) and private (non-profit and for-profit organizations)</p> <p>Community case: reported by community health workers, administrators and other personnel operating at village and community level</p> <p>Reporting completeness: percentage of health facilities reporting data within a nationally established time frame out of the total existing facilities expected to report</p> <p>Since it is difficult to get the actual number of true “severe malaria” according to WHO definition, in-patient cases are often taken as a surrogated numerator.</p>			
Purpose	To measure the clinical load of progression from uncomplicated to severe malaria and the burden of the disease			
Data collection				
<i>Method</i>	<i>Tools</i>	<i>Level</i>	<i>Frequency</i>	
Health management information service: routine or integrated disease surveillance or malaria surveillance. Absolute numbers for numerator and denominator and reporting completeness must be reported with the rate.	Health facility records, registers and community forms	District, province, region, country	Annually (at global level)	
Interpretation and use	The indicator reflects one of the main expected outcomes of early diagnosis and treatment of uncomplicated malaria. It helps planning and resource allocation. The percentage is influenced by treatment-seeking behaviour, by malaria treatment practices at both community and facility levels and by access to health care.			
Reference	<i>Framework for monitoring progress and evaluating outcomes and impact.</i> Geneva, World Health Organization/Roll Back Malaria, 2000 (WHO/CDS/RBM/2000.25), pp. 10–13.			

7. Indicator **Percentage of health facilities reporting no stockout of antimalarial medicines and diagnostics**

Calculation	<p>Numerator: Number of health facilities, in areas at risk for malaria, reporting no stockouts of first-line antimalarial medicines and RDTs for more than one week in a month</p> <p>Denominator: Total number of health facilities reporting, supervised or surveyed in the same areas at risk for malaria x 100</p>			
Definitions of key terms	<p><i>First-line antimalarial medicine:</i> antimalarial medicine recommended by national treatment guidelines</p> <p><i>Stock-out period:</i> it should be over 1 week in a month. However, some countries may report in number of days based on the their reporting system</p> <p><i>RDT:</i> consistent information on availability and use of RDT is vital for interpretation of the data</p>			
Purpose	To measure health system capacity for procurement and supply-chain management of antimalarial medicines and diagnostics			
Data collection				
<i>Method</i>	<i>Tools</i>	<i>Level</i>	<i>Frequency</i>	
Health management information service: routine	Health facility records and registers	National, district or sub-national	Quarterly	
Supervisory reports	Supervisory reports		Annually	
Facility survey	Survey reports		Every 2–3 years	
Interpretation and use	Reliability can vary according to the data collection method. Data from health facilities can be inconsistent or distorted; supervisory team reports should be more accurate. Monitoring the availability of antimalarial medicine and RDTs in the health facility promotes direct involvement of health officers in ensuring sustainable medicine distribution and calls the attention of supervisory teams at all levels to this crucial aspect of intervention.			
Reference	<i>Framework for monitoring progress and evaluating outcomes and impact.</i> Geneva, World Health Organization/Roll Back Malaria, 2000 (WHO/CDS/RBM/2000.25), pp. 10–13.			

8. Indicator **Proportion of malaria cases treated promptly and appropriately**

Calculation	<p>Numerator: Number of children aged under 5 and other target groups with fever or malaria (finger or heel prick) during the 2 weeks before the survey who received efficacious antimalarial medicines within 24 hours of onset of fever</p> <p>Denominator: Total number of children aged under 5 and other target groups with fever or malaria (finger or heel prick) during the previous 2 weeks in the population sampled X 100</p>			
Definitions of key terms	<p>Malaria: in countries with high transmission, such as in tropical Africa, a large proportion of fevers in children are due to malaria. In settings of low endemicity, fever is more likely to be due to other causes, and therefore malaria should be diagnosed before treatment, as malaria episodes affect older persons too.</p> <p>Efficacious: antimalarial medicines known to have a therapeutic efficacy of at least 90% in the survey area</p> <p>Disaggregated data analysis to determine the percentage of under 5 with fever who were finger or heel pricked that received efficacious antimalarial treatment</p>			
Purpose	To measure coverage with prompt, appropriate case management especially in areas with <i>P. falciparum</i> malaria.			
Data collection				
<i>Method</i>	<i>Tools</i>	<i>Level</i>	<i>Frequency</i>	
Household surveys: Malaria Indicator Survey, Macro International Demographic and Health Surveys, UNICEF Multiple Indicator Cluster Surveys and others. Analysis and reporting of data by urban and rural setting and by province is recommended.	Questionnaires, data tabulations and survey reports	Country or sub-national	Every 2–3 years (Malaria Indicator Surveys and others); every 5 years (Demographic and Health Surveys, Multiple Indicator Cluster Surveys)	
Interpretation and use	The indicator facilitates assessment of changes in health-seeking behaviour and the availability of and timely access to appropriate antimalarial medicines. Answers to questionnaires provide supplementary information on the type of medicine (e.g. artemisinin-based combination treatments, chloroquine, sulfadoxine-pyrimethamine) and from where (health facility, home, shop, other) it was obtained. The appropriate antimalarial medicine (artemisinin-based combination treatments or other) should be based on the prevalence of plasmodium and the expected therapeutic efficacy of the medicine at the time and place of the survey. Use of local terms for malaria in the survey questionnaires increases the specificity of the survey for detecting true clinical malaria episodes.			
References	<ol style="list-style-type: none"> 1. <i>Scaling up home-based management of malaria: from research to implementation</i>. Geneva, World Health Organization, 2004 (WHO/HTM/MAL/2004.1096; TDR/IDE/HMM/04.1), pp. 86–91 2. Guidelines for core population coverage indicators for RBM: to be obtained from household surveys. Geneva, Roll Back Malaria/MEASURE Evaluation/World Health Organization/UNICEF, 2004, p. 12. 			

ANNEX 4

Malaria patient card

The purpose of the malaria patient card is to facilitate patient consultation (from clinical assessment to diagnosis and treatment) and the recording of information in the malaria register, since the card will show all the malaria-related information about the patient, whether or not a drug was dispensed. This card may be taken home or left at the health facility at the end of the consultation to enable the information to be recorded in the malaria register.

Explanatory notes

The following explanatory notes for completing the malaria patient card relate to the example of such a card shown in Appendix 1.

Identification of patient

Record the patient's name, age, sex, outpatient department patient number and whether the patient is pregnant. If the patient is pregnant, tick the box corresponding to the trimester of pregnancy so that appropriate treatment is given.

1. Clinical assessment of malaria

Establish and record the duration of fever, and check for and record a few common signs and symptoms to exclude a diagnosis of severe malaria.

2. Laboratory examination

Tick whether a laboratory examination has been performed; if it has, either by microscopy or rapid diagnostic test, tick the result (positive or negative). If the malaria species was identified, tick "F" for falciparum, "V" for vivax, "M" for mixed infection (i.e. falciparum and vivax or any other plasmodium), "O" for other (i.e. plasmodia other than falciparum and vivax) and "U" for unidentified when the species was not identified.

3. Diagnosis

This section is to be filled in after a diagnosis has been made either clinically or in the laboratory.

- (a) Clinical or probable malaria: Tick if the patient was suspected of having malaria clinically or had a negative test but was treated as having malaria.
- (b) Confirmed malaria: Tick if the patient was confirmed by microscopy or a rapid diagnostic test as having malaria.
- (c) Re-treatment (treatment failure): Tick if the patient returned to the health unit within 14 days after completing a full course of an effective antimalarial treatment (artemisinin-based combination treatment) and still had malaria parasites in blood.
- (d) Severe malaria: Tick if the patient had malaria with any sign or symptom of severe malaria.

4. Treatment prescribed

Information on the drug prescribed and the dosage should be recorded here. It is advisable to include the name of the drug and dosage.

5. Treatment dispensed

This section should be filled in after the patient has been to the dispensary or pharmacy. Tick “Yes” only if the prescribed medicine in the right amount was dispensed to the patient at the health facility; tick “No” if it was not dispensed.

6. Action taken

The health worker who took the consultation should complete this section. Tick:

- (a) Sent home: if the patient was treated as an outpatient and sent home.
- (b) Referred: if a patient with probable or confirmed severe malaria was referred to another health facility for further management.
- (c) Admitted: if a patient with severe malaria was admitted for further treatment.

Appendix 1

Example of a malaria patient card

Province/Region District Date

Health unit Patient's OPD No.

Name

Age Sex Pregnant NO
 YES 1st 2nd 3rd trimester

1. Clinical assessment of malaria

Duration of fever (days before visit) 1 2 > 2

Ask and check for signs of severe malaria (tick ✓):

If signs of severe malaria:

Multiple convulsions Impaired consciousness or lethargy
 Others, specify

If other signs of severe disease:

Vomiting everything
 Unable to walk or to sit unassisted

2. Laboratory examination

- Laboratory examination: YES NO
- Blood smear: positive negative
- Rapid diagnostic test: positive negative
- Malaria species:

P. falciparum *P. vivax* mixed infection others not identified

3. Diagnosis

Clinical or probable malaria Confirmed malaria Re-treatment Severe malaria

4. Treatment prescribed _____

5. Treatment dispensed YES NO
 Amount

6. Action taken

Sent home Referred Admitted

ANNEX 5

Health unit malaria case register

It is recommended that health units maintain separate registers of malaria cases, as this facilitates follow-up and improves malaria case management. Only patients treated for malaria should be included in the health unit malaria case register, including those for whom test results were negative but who were treated for malaria.

It is important that every patient treated for malaria is registered in the health unit malaria case register. The register provides a means of recording the basic information that has been collected on the malaria patient card for each patient treated for malaria. The information recorded can then be summarized in monthly summary reports. The information contained on the patient card should be transferred to the malaria register at the end of a consultation, i.e. after the patient has received a prescription or a drug has been dispensed.

Explanatory notes

The following explanatory notes for completing the health unit malaria case register relate to the model register shown in Appendix 1.

The malaria case register consists of six main columns: patient details; laboratory test; outpatient malaria diagnosis; outpatient malaria treatment and action; inpatient malaria cases; and malaria cases treated at community level. These columns and their subdivisions are explained below.

1. Patient details

This first column enables demographic information to be recorded to allow each patient to be identified. Record the patient's outpatient department or inpatient department number, the date on which the patient was seen, the patient's name, age and sex, whether the patient was pregnant and the patient's address.

2. Laboratory test

The second column enables laboratory test information to be recorded. If the patient was tested for malaria parasites with rapid diagnostic tests or microscopy, indicate by ticking "P" (positive) or "N" (negative). Next, indicate the parasite species: "F" for falciparum, "V" for vivax, "M" for mixed infection (falciparum and vivax or any other plasmodium), "O" for other (any species other than falciparum or vivax) and "U" for unknown in cases where the species was not identified or written on the patient card.

3. Outpatient malaria diagnosis

In this third column, the outpatient diagnosis made by the clinician should be recorded. Record the diagnosis as written on the patient card as uncomplicated or severe malaria. If the diagnosis of uncomplicated malaria refers to a new case diagnosed clinically, then tick "probable"; if it has been diagnosed

parasitologically, then tick “confirmed”. Alternatively, if the diagnosed patient has returned to the health unit and is re-treated, then tick “ACT re-treatment”. If the patient has been referred because of severe malaria, in the “severe malaria referred cases” column, tick “probable” if the patient has been clinically diagnosed; if he or she has been parasitologically diagnosed, tick “confirmed”.

Subcolumns under the column “Uncomplicated malaria cases”:

New cases:

- Probable: cases treated as malaria on the basis of clinical diagnosis or despite a negative malaria smear or a negative rapid diagnostic test.
- Confirmed: cases of malaria confirmed by microscopy or rapid diagnostic test.

ACT re-treatment cases: patients who have parasitologically confirmed malaria and who are re-treated with ACTs despite having received a full course of an effective ACT treatment during the previous two weeks.

4. Outpatient malaria treatment and action

This column enables the recording of the medicine prescribed and the action taken. Write the name of the medicine prescribed, indicate by ticking “Yes” if the patient received the medicine at the health facility dispensary or pharmacy and “No” if the patient did not receive the prescribed medicine. Then record what action was taken by the clinician after seeing the patient: tick “H” for sent home, “R” for referral to another facility or “A” for admission to the health facility.

5. Inpatient malaria cases

This fifth column should be completed if patients are admitted at the health facility. The information should be completed at discharge or death of the patient on the ward. It is important that information from the ward is recorded in a timely manner on the malaria register on the day the patient is discharged.

6. Malaria cases treated at community level

This sixth column should be completed from information gathered by the community-based providers if the health unit has a surrounding community-based system for delivering treatment for malaria and a programme in place for malaria case management, and if it provides supervision and supplies to those providers. Community-based providers should record the total number of those tested by rapid diagnostic tests (RDTs), of those not tested, of those testing negative, of those testing positive, and the total number of cases seen at the community level.

It is also recommended that this section be used as a stand-alone malaria register by the community-based providers, who should record the information required. This community malaria register should include the first column group (Patient details) contained in the health unit malaria cases register, in which the patient’s details should be recorded, a column for non-tested cases, a column for RDT-tested cases, subdivided into two columns for positive or negative cases, in which the laboratory results should be recorded, and a column indicating treatment, subdivided into three columns for not treated, treated

or referred. A simple community register would therefore comprise only three column groups: patient details; non-tested and RDT-tested cases; and treatment. Community-based providers should record the minimum information necessary to enable them to report the total number of patients tested by rapid diagnostic test, the total number of those not tested, the total number of negative tests, the total number of positive tests and the total number of cases seen at the community level for the month by age categories. This information should be reported each month to the first-level health facility, to a person in charge of community activities.

ANNEX 6

Health unit malaria monthly summary report form

The purpose of the health unit malaria monthly summary report form is to summarize each month the basic information useful for malaria case management that can be retrieved from the health unit malaria case register (see Annex 5). To ensure that the reporting health facility is clearly identified, the month and year of reporting, the name of the health unit and the district should be indicated on the form.

Explanatory notes

The following explanatory notes for completing the health unit malaria monthly summary report form relate to the model of such a form shown in Appendix 1A (Version 1). The form shown in Appendix 1B (Version 2) is an adaptation of that shown in Appendix 1A, and is for use in those countries in the WHO African Region in which malaria patients may, for reporting purposes, be divided into two age groups: below 5 years and above 5 years.

COLUMNS

The report form consists of 7 main columns:

- age group, sex and pregnancy status;
- total all-cause cases;
- laboratory tests (outpatient department and inpatient department);
- total malaria cases not tested (OPD and IPD);
- outpatient malaria cases;
- inpatient malaria cases; and
- malaria cases treated at community level.

The following notes provide guidance on filling in these columns and their subcolumns. Health facilities that do not have admission facilities or have no malaria case management at the community level need not fill in the two final sections: inpatient malaria cases; and malaria cases treated at community level.

1. Age group, sex and pregnancy status

All the information obtained from the health unit malaria cases register should be entered according to age group, i.e. < 5 years, 5–14 years and 15+ years, according to the sex of the patient (male or female) and according to the pregnancy status of female patients.

2. Total all-cause cases

This column enables the total number of cases of all diseases seen in the health facility during the reporting month to be recorded. Enter the total number of cases by age category seen in both the outpatient department (OPD) and the inpatient department (IPD) and the total number of deaths from all diseases.

3. Laboratory tests (OPD and IPD)

In this column, record the total number for the month of those cases tested by rapid diagnostic test (RDT) or microscopy, the total number testing positive, the total number of cases according to

malaria parasite species and the total number of malaria cases that were not tested, for both the outpatient and the inpatient departments.

4. *Total malaria cases not tested (OPD and IPD)*

In here, should be entered the total number of patients for whom no malaria test was performed.

5. *Outpatient malaria cases*

This column enables the recording of the total number of uncomplicated and severe outpatient malaria cases seen (both probable and confirmed), the total number of re-treated cases receiving artemisinin-based combination therapies (ACTs), and the total number of uncomplicated malaria cases receiving ACTs according to each age category. In the column entitled “Total outpatient malaria cases”, the sum total of all uncomplicated and severe malaria cases seen in the outpatient department should be entered.

6. *Inpatient malaria cases*

Health units that have admission facilities for inpatients should complete this column, which provides for a monthly summary of the total number of probable and confirmed cases of severe malaria, the total number of inpatient malaria cases (both probable and confirmed), the total number of probable and confirmed cases of malaria death, the total number of malaria-attributed deaths (probable and confirmed malaria deaths) among admitted cases, and the total number of transfused patients and paediatric transfusions due to malaria.

7. *Malaria cases treated at community level*

This column should be completed if the reporting health unit has a surrounding community-based system for delivering treatment for malaria and a programme in place for malaria case management, and if it provides supervision and supplies to the community-based providers. Record the total number of those tested by rapid diagnostic tests (RDTs), the total number of those not tested, the total number of those testing positive, the total number of those testing negative, and total number of cases treated at the community level for the month.

ROWS

The report form consists of 8 rows:

- < 5 years,
- 5–14 years,
- 15+ years,
- subtotal,
- male,
- female,
- pregnancy and
- total.

Pregnancy

This row should be completed for pregnant women with malaria seen in the outpatient department or for pregnant women with severe malaria who are admitted. An effort should also be made to record the number of all pregnant women admitted to the health unit and the total number of pregnant women who died of all causes in the same reporting health unit (total number of pregnant women admitted and total number of pregnant women who died in the health unit).

ANNEX 7

District malaria monthly summary report form

The purpose of the district malaria monthly summary report form is to collect the information supplied by all the health units in the district. The form summarizes all the information submitted by health units on the health unit malaria monthly summary report forms for both malaria outpatients and inpatients (see [Annex 6](#)). The month and year of reporting and the name of the district and/or province must be indicated clearly at the top of the form for proper identification at the subnational level. The form should be completed by the district data manager and cross-checked by the district malaria focal person before being sent to the national level.

Explanatory notes

The following explanatory notes for completing the district malaria monthly summary report form relate to the model form shown in Appendix 1.

Columns

The report form consists of six main columns, for the completion of which the following notes provide guidance. The first column is divided into two subcolumns:

1. Health unit / age / sex / pregnancy status

1a: Health unit name: Enter in this column the names of the health units reporting during the month.

1b: Age group, sex and pregnancy status: All the information provided by each health unit should be entered according to age group, i.e. < 5 years, 5–14 years and ≥15+ years, according to the sex of the patient (male or female) and according to the pregnancy status of female patients.

2. Total all-cause cases

Total all-cause outpatient cases: Total number of patients (all diseases) seen in the outpatient department of the reporting health unit in the district during the reporting month.

Total all-cause inpatient cases: Total number of patients (all diseases) admitted to the reporting health unit during the reporting month.

Total all-cause deaths: Total number of deaths that occurred from all causes in the reporting health unit during the reporting month.

3. Laboratory tests (OPD and IPD)

RDT (rapid diagnostic tests): total number of tests examined and total number testing positive.

Microscopy: total number of tests examined and total number testing positive.

Parasite species: total numbers of different species identified during the reporting month: F for *P. falciparum*, V for *P. vivax*, M for mixed infection, O for other species, U for unknown; could be adapted to the epidemiological situation in the country.

Total malaria cases not tested (OPD and IPD): total number of patients in the reporting health unit for whom no malaria test was performed.

4. Outpatient malaria cases

Uncomplicated malaria cases:

New cases: total of all uncomplicated malaria cases seen in the outpatient department; these cases should be recorded as probable, confirmed or re-treated cases (re-treated cases in the column entitled “ACT treatment failures”), according to the health facility monthly summary report form.

Severe malaria cases referred or admitted: in this column, record the probable and confirmed severe malaria cases seen in the outpatient departments of all health units reporting to the district.

Total outpatient malaria cases: in this column, add up all the cases in columns 5a and 5b to obtain the total number of all malaria cases seen in the outpatient departments of all the reporting health units.

Total patients receiving ACTs: in this column, record the total number of patients who received ACTs from the health unit according to the monthly summary report form for the reporting health unit.

Malaria cases referred from OPD: in this column, record the total number of severe malaria cases that were referred to another health unit according to the reporting health unit’s report form.

5. Inpatient malaria cases

This section should be completed for all the health units with admission facilities in the district.

Severe malaria cases: in this column, fill in the total numbers of probable and confirmed severe malaria cases, as submitted by the health unit.

Total inpatient malaria cases: in this column, record the total number of severe cases admitted in the health units (total of the two subcolumns under the column “Severe malaria cases”).

Death: in this column record the total number of patients with probable and confirmed malaria who died of malaria, as reported by the health units.

Total malaria-attributed deaths: in this column, fill in the total of the two subcolumns under the column “Death”.

Total paediatric transfused cases: in this column, enter the total number of children with malaria who received transfusions.

6. Malaria cases treated at community level

This section should be completed by entering the information provided by all those health units reporting on malaria treatment and case management at the community level.

RDT-tested cases: in this column, record the total number of cases with positive RDT results and the total number with negative RDT results.

Total malaria cases treated: in this column, record the total number of malaria cases treated at the community level as reported by the health unit.

Rows

The report form consists of seven rows for each health unit: < 5 years, 5–14 years, 15+ years, subtotal, male, female, and pregnancy.

Pregnancy: Complete each column for malaria in pregnant women.

Total A–E: Sum all the figures to get totals for each column for each health unit.

Grand total: Add up the totals for each health unit entered to obtain the overall totals for the district.

Depending on the number of health units in the district, there may be many grand totals, which should be summed.

ANNEX 8

Model checklists for malaria case management supervision

A. Trained health worker performance in case management of malaria (outpatient observation checklist)

Country/province/district Date

Health unit Observation number

Designation of health worker

Trained in malaria or integrated management of childhood illness

Date of training

Observer Designation

Initial/follow-up visit

Trained in malaria or integrated management of childhood illness

1. Reception

Does the health worker welcome the caregiver or patient? YES NO

Does he or she invite the caregiver or patient to sit down? YES NO

Does he or she determine the patient's age? YES NO

Does he or she determine the weight of the patient? YES NO

2. Does the health worker ask about and look for general danger signs and other signs of severe malaria?

Change in behaviour, altered consciousness or coma YES NO

Convulsions YES NO

Severe anaemia YES NO

Reduced urinary output or dark urine YES NO

Spontaneous bleeding YES NO

Prostration YES NO

Inability to drink YES NO

3. Does the health worker ask questions about

Presence and duration of fever? YES NO

History of travel to malarious area? YES NO

Diarrhoea? YES NO

- Vomiting? YES NO
 Cough? YES NO
 Other symptoms (discharge from ear, measles)? YES NO
 Treatment at home before coming to this health facility? YES NO
 Treatment given at other health facilities? YES NO

4. Does the health worker

- Determine the patient's temperature? YES NO
 Look for fast breathing or chest indrawing? YES NO
 Examine the patient for evidence of anaemia? YES NO
 Look for signs of other severe diseases
 (e.g. neck stiffness, dehydration)? YES NO
 Request a blood smear for malaria parasites (where appropriate)? YES NO

5. Does the health worker

- Appropriately classify the illness? YES NO
 Decide on correct case management, including referral? YES NO

6. Treatment

- Is an antimalarial drug appropriately prescribed? YES NO
 Is the drug prescribed in accordance with national guidelines? YES NO
 Is the dosage correct? YES NO
 Is the first dose given at the health facility? YES NO
 Are additional drugs prescribed? YES NO
 If yes, specify

7. Did the health worker

- Tell or advise the caregiver or patient what is wrong with the patient? YES NO
 Advise the caregiver or patient on how to take the prescribed drugs? YES NO
 Check that the patient has correctly understood the prescription? YES NO
 Advise antipyretics in case of high fever? YES NO
 Advise about supportive treatment? YES NO
 Advise on when to return? YES NO
 Advise on preventive measures? YES NO
 Check the understanding of the caregiver or patient? YES NO
 Ask if the caregiver or patient has any questions? YES NO

8. Overall assessment and management performance:

- Bad Fair Good Excellent

9. General remarks

B. Monitoring and evaluation of patient care: interview with caregiver or patient

Country/province/district..... Date

Health unit Observation number

Interviewer.....

1. Do you know what is wrong with you/your child? YES NO
(Explore)

2. Was any medication prescribed? YES NO

3. *How much of this (antimalarial) drug are you going to give or take?

How many times a day? Correct Not correct

For how long? Correct Not correct

How much of this (antipyretic) drug are you going to give or take?
 Correct Not correct

How many times a day? Correct Not correct

For how long? Correct Not correct

4. When will you return to the health facility?

If the patient gets sicker Correct Not correct

If the patient is unable to drink Correct Not correct

After 2 days if fever continues Correct Not correct

If there is persistent vomiting Correct Not correct

If there are convulsions Correct Not correct

Others (specify)

5. How will you care for the patient at home? (Do not suggest an answer):

Give the drug for fever YES NO

Give lukewarm or sponge bath YES NO

Continue feeding YES NO

Others (specify)

6. Are you satisfied with the level of service in this place? YES NO

7. How do you think the service could be improved?

* The interviewee is expected to assess the correctness of the patient's responses

3. Checklist of unit support and activities

Country/province/district..... Date

Health unit Observation number

Level of unit.....

Assess conditions: star (*) problems identified	Solve identified problems: tick solutions
<p>Space and equipment</p> <ol style="list-style-type: none"> 1. Examination area? 2. Lighting of examination area? 3. Space to see patient? 4. Chair and table for health worker? 5. Functioning weighing scale? 6. Thermometer? 7. Watch or other timing device? 8. Malaria diagnosis (slides/rapid diagnostic tests) 9. Treatment guidelines? 10. Antimalarial drug dosing chart on wall? 11. Patient record cards? 12. Malaria patient register? 13. Supplies for assessing patient? 	<p>Space and equipment</p> <ul style="list-style-type: none"> • Reorganize space and help health worker set up examination area. • Identify minimal requirements for furniture that could be moved to the examination area. • Report needs to district level (scale, timing device, thermometers, guidelines, charts, patient record cards). <p>Please describe what has been proposed or done to solve the problems identified:</p>
<p>Organization of case management tasks</p> <ol style="list-style-type: none"> 1. Register patients, manages triage/patient flow? 2. Weigh patient? 3. Take body temperature? 4. Test patient for malaria parasites? 5. Are drugs dispensed? 6. Instructions on how medication should be given? 7. Give first dose of drug? 8. Complete patient records? 	<p>Organization of case management tasks</p> <p>Tasks not routinely carried out well by trained workers:</p> <ul style="list-style-type: none"> • Find out why tasks are not carried out well. • Determine whether the task is carried out by other staff. • Determine whether the way in which the task is carried out by other staff interferes with work of trained health worker. <p>Solve problems that interfere with case management of malaria, e.g.:</p> <ul style="list-style-type: none"> • Help trained worker to train other staff. • Organize patient flow. • Identify ways to make case management more efficient, less time-consuming. <p>Help trained/untrained staff to determine how to ensure case management tasks can be carried out.</p>
<p>Clinic and referral services</p> <ol style="list-style-type: none"> 1. Clinic open during all scheduled hours? 2. Waiting time for patients? 3. Is patient load balanced by staff distribution during clinic hours? 4. Pharmacy services available during open hours? 5. Malaria diagnostic services available? 6. Preventive and control services provided? 7. Immunization services available every day? 8. Referral care possible within reasonable time? 9. Referral care considered adequate? 	<p>Clinic and referral services</p> <p>Reconfirm scheduled clinic hours for services offered.</p> <p>Discuss difficulties encountered in providing essential services every day and identify possible solutions.</p> <p>Review what to do when referral is not possible.</p> <p>Report unsolved problems to district level.</p>

Assess conditions: star (*) problems identified	Solve identified problems: tick solutions
<p>Management of drugs and other supplies</p> <ol style="list-style-type: none"> 1. Organization of stocks 2. Drugs, supplies stored securely? 3. Drugs in a dry place? 4. Quinine in a dark place? 5. Drug stock control in place? 6. Source of drugs? 	<p>Management of drugs and other supplies</p> <p>Suggest how to:</p> <ul style="list-style-type: none"> • secure store • repair leaks in store. <p>Report need for drug stock control to district level.</p>
<p>Availability of drugs and other supplies in stock on day of visit</p> <ol style="list-style-type: none"> 1. First-line antimalarial drug 2. Second-line antimalarial drug 3. Quinine tablets 4. Quinine injection 5. Sterile syringes 6. Sterile needles 7. Butterfly needles and cannulae 8. Antipyretics 9. Cotton swabs 10. Skin disinfectant 11. Intravenous administration sets 12. Nasogastric tubes 13. Dextrose 5%, 10% and 50% 14. Normal saline 15. Intravenous and rectal diazepam <p>Check for expiration time.</p>	<p>Availability of drugs and other supplies in stock on day of visit</p> <p>Determine problem in availability of drugs and other supplies e.g.:</p> <ul style="list-style-type: none"> • needs not adequately assessed • inadequate records and ordering • drugs not used rationally • not enough drugs available in central store • high seasonal demand • no transport. <p>Identify appropriate solution, e.g.:</p> <ul style="list-style-type: none"> • Review and give practice in using drug stock card or book. • Review rational use of drugs with persons responsible for prescribing. • Identify ways to combine use of transport. <p>Report stock shortages to district level.</p>
<p>Quality of records</p> <ol style="list-style-type: none"> 1. Are individual patient records or registers maintained? 2. If yes, assess whether most include: <ul style="list-style-type: none"> • diagnosis or classification • treatment prescribed • treatment given • blood slide result • follow-up, indicating date. 	<p>Quality of records</p> <ul style="list-style-type: none"> • Identify feasible way to make patient records available. • Provide example of appropriate record. • Have health worker practise recording information on one case; give feedback.
<p>Laboratory facility</p> <ol style="list-style-type: none"> 1. Microscope available and functional? 2. Slides available? 3. Reagents available? 4. Rapid diagnostic tests available? 5. Register of results exists? 6. Light source available? <p>Check for expiration time.</p>	<p>Laboratory facility</p> <ul style="list-style-type: none"> • Identify feasible ways of getting microscope. • Identify need for training to improve skills. • Find ways of ensuring availability of supplies. • Check whether light microscope can be used where there is no electricity.

ANNEX 9**Model suspect adverse drug reaction report form**

(Insert logo and address of ministry of health)

Serious Adverse Drug Reaction Identification No.

PATIENT INFORMATIONName Age Date of birth (Day/Month/Year): / /
Sex M F

Patient's address:

*If female, is the patient pregnant?*YES – if yes: date of last menstrual period / / NO Not sure

Weight..... kg Height..... m

NATURE OF ADVERSE EVENT (cross those that apply)Death Life-threatening Hospitalization Permanent disability Congenital anomaly

Other: (specify).....

DATE OF OCCURRENCE (Day/Month/Year): / /

DESCRIBE THE ADVERSE EVENT IN DETAIL (INCLUDING RELEVANT LABORATORY RESULTS)

DESCRIBE HOW THE REACTION WAS TREATED:

OUTCOME OF REACTION:Recovered completely Not yet recovered Recovered with long term consequences

DATE OF RECOVERY (Day/Month/Year): / /

MEDICINES (List the medicines suspected of causing the reaction as well as all concomitant medicines)

Brand name & Batch No. (List suspected drug first)	Daily dosage	Route	Date started	Date stopped	Reasons for use
		 / / / /	
		 / / / /	

COMMENTS: (e.g. Include relevant medical history, drug allergies, previous exposure to similar drugs, other lab data)

Reporting doctor, pharmacist or health care professional

NAME: QUALIFICATIONS.....

ADDRESS:

.....

SIGNATURE: TEL:

DATE OF THIS REPORT (Day/Month/Year): / /.....

ADVICE ABOUT VOLUNTARY REPORTING

Please report: suspected adverse drug reactions and interactions with all drugs;

.....

Serious adverse medicine reactions include all cases resulting in:

- death;
- life-threatening events;
- permanent disability or incapacity;
- congenital anomalies;
- hospitalization or prolongation of hospitalization as a result of the event;
- other events, which you may deem to be serious or important:

.....

Report even if:

- you are not certain the product caused the reaction;
- you do not have all the details.

Important numbers and address:

.....

.....

Who to report to: Please send this report to the Pharmacovigilance co-ordinator at your nearest district hospital

.....

.....

.....

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

Your support of the adverse drug reaction monitoring programme is much appreciated.

Information supplied by you will contribute to the improvement of drug safety and therapy in our country

Appendix 1

Checklist for investigation of suspect adverse drug reaction

1. Confirm information in report:

- obtain patient's medical file (or other clinical record);
- check details about the patient and the event from the medical file and document the information;
- obtain any details missing from the suspect adverse drug reaction report form;
- identify any other cases that should be included in the investigation.

2. Investigate and collect data about the patient:

- history of drug use (including the use of over-the-counter and traditional medicines);
- medical history, including prior history of similar reactions or allergies;
- family history of similar events.

3. Investigate and collect data about the event:

- history, clinical description, any relevant laboratory results and diagnosis of the event;
- treatment, whether hospitalized and outcome.

4. Investigate and collect data about the suspected drug(s):

- conditions of storage at facility and expiry date.

5. Investigate and collect data about other people:

- whether others received the same drug and became ill (assess health facility ledgers);
- whether others had similar symptoms (may need case definition); if so, exposure to suspect drug(s);
- conditions at the local health facility.

6. Assess the service by asking about:

- drug storage and prescription;
- details of training in diagnosis and treatment;
- whether the number of treatments was higher than normal.

7. Formulate a working hypothesis about the probable cause(s) of the event

8. Test the hypothesis:

- does the case distribution match the working hypothesis?
- occasionally, laboratory tests may help.

9. Conclude the investigation:

- assess the causal association with the suspected drug(s);
- take corrective action, and recommend further action (see section 11).

10. Assess outcome of actions or lack of action taken and assess the impact of any corrective action taken (where appropriate).

For further information, please contact:

Global Malaria Programme
World Health Organization
20, avenue Appia – CH-1211 Geneva 27
infogmp@who.int
www.who.int/malaria

