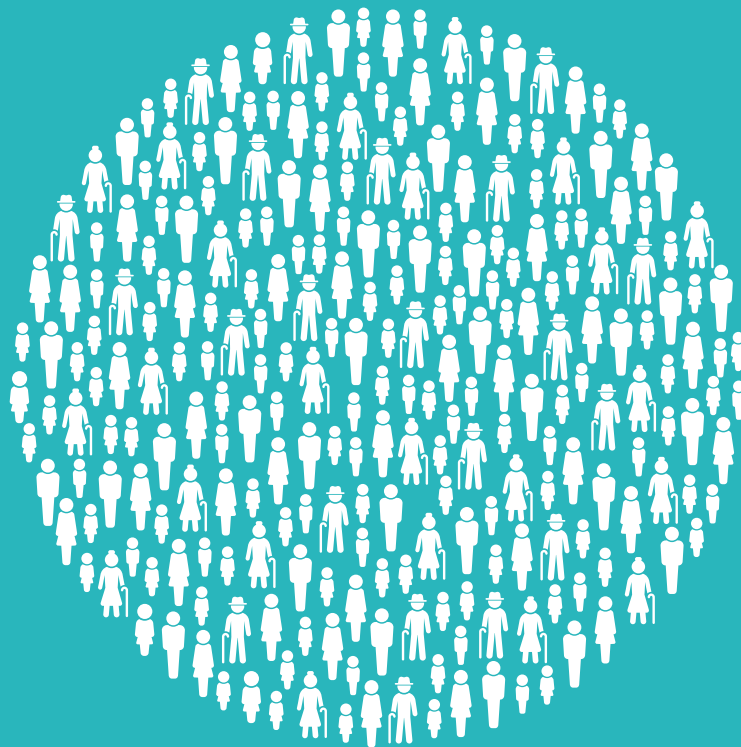


Mass drug administration for falciparum malaria



A practical field manual

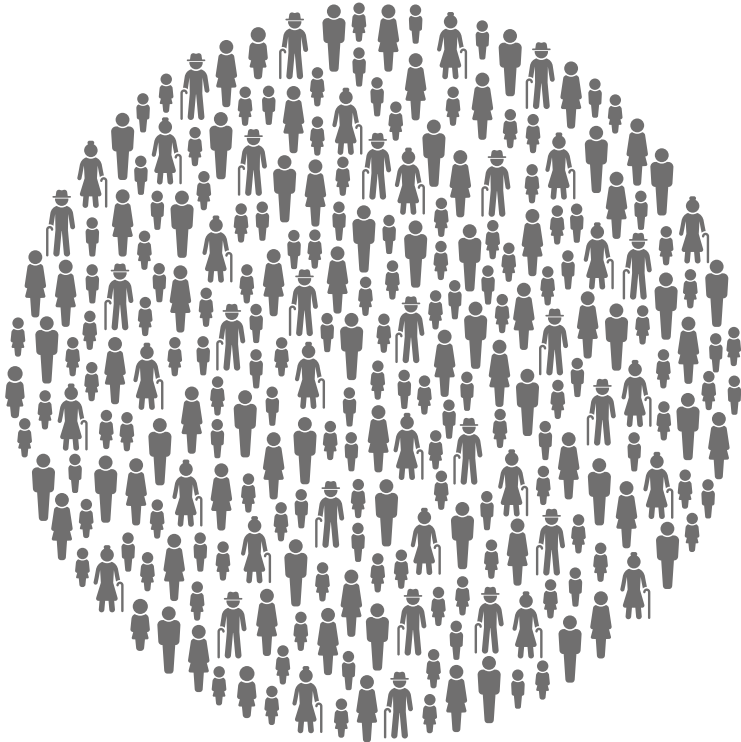


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Mass drug administration for falciparum malaria



A practical field manual



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Acknowledgements

This operational manual on mass drug administration (MDA) for malaria is based on practical field experience in the great majority of MDA operations that have been completed over the past 10 years in malaria-endemic countries.

The main author was Dr Carolina Nanclares (Médecins Sans Frontières, Spain), who prepared an excellent first draft and finalized it after careful consideration of the suggestions of multiple reviewers. Dr Nanclares based the first draft on experience and lessons learnt during widescale MDA in Sierra Leone during the epidemic of Ebola virus disease, completed in 2014–2015. The following colleagues from MSF Spain who participated in that campaign provided input on the first draft: Jonathan Caplan, Fernanda Falero, Adriana Ferracin Kleivan, Segimon Garcia, Maria Green, Yves Houedakor, Cristina Imaz, Nines Lima and Charlotte Oliveira. The WHO Global Malaria Programme then convened a drafting committee consisting of technical resource officers who contributed to control of malaria by MDA and research in: Cambodia, Comoros, Mozambique, Myanmar, Sierra Leone, Thailand, Viet Nam and Zambia. The first draft was sent by email to all the invited participants one month before the meeting, and all input received before the meeting was included in the second version, which was used as the basis of the work of the drafting committee.

The meeting was held on 22–23 November 2016 in Geneva, where the members of the committee (listed below) were divided into four working groups to review and finalize the practical aspects of the different sections of the manual. During the last session of the meeting, the groups presented their conclusions in plenary, bringing to resolution the points that required consensus. Dr Nanclares, as rapporteur of the meeting, then compiled a third version that included all the input from the four working groups, which was circulated to all participants by email for final review. The text of the manual is the result of a fourth round of reviews by members of the drafting committee and the WHO Secretariat.

We are very grateful to the following members of the drafting committee, who graciously reviewed all the sections of the report in several rounds, providing substantive comments that were instrumental for its finalization and improvement: Gilles Delmas (Mahidol-Oxford Tropical Medicine Research unit, Thailand), Stephan Duparc (Medicines for Malaria Venture, Switzerland), Busiku Hamainza (National Malaria Control Centre, Zambia), James Heaton (Mahidol-Oxford Tropical Medicine Research unit, Myanmar), Umu Jalloh (Pharmacy Board, Sierra Leone), Anitta Renitta Yokoe Kamara (National Malaria Control Programme, Ministry of Health and Sanitation, Sierra Leone), Calveston Machila (District Medical Office, Zambia), Joseph Mberikunashe (National Malaria Programme Control, Zimbabwe), Thuy-Nhien Thanh Nguyen (Centre for Tropical Medicine, Viet Nam), Francisco Saute (Manhiça Health Research Center, Mozambique), Jianping Song (Guangzhou University of Chinese Medicine, China) and Khieu Virak (National Centre for Parasitology, Entomology and Malaria Control, Cambodia).

The draft manual also received input from the WHO Malaria Policy Advisory Committee at its session on 22–24 March 2017, which, with additional suggestions from the WHO Secretariat at the Global Malaria Programme, were taken into account in the final version of the document.

At WHO, Andrea Bosman, Global Malaria Programme, coordinated preparation of the manual and represented the WHO Secretariat in the the drafting committee. Precious contributions were also made by Dr Maru Aregawi, Peter Olumese and Silvia Schwarte, Global Malaria Programme, and by Prabhjot Singh, WHO Regional Office for the Americas.

Funding for the production of this report was provided the Bill & Melinda Gates Foundation.



Abbreviations and acronyms

ACT artemisinin-based combination therapy

ADR adverse drug reaction

CHW community health workers

DOT directly observed treatment

EVD Ebola virus disease

G6PD glucose-6-phosphate dehydrogenase

MDA mass drug administration

Executive summary

Mass drug administration (MDA) consists of administering a full therapeutic course of antimalarial medicine (irrespective of the presence of symptoms or infection) to a defined population living in a defined geographical area (except for those for whom the medicine is contraindicated) at approximately the same time and often repeated at intervals. Recent progress in malaria control, including the use of others forms of preventive chemotherapy such as intermittent prevent treatment of malaria in pregnancy and seasonal malaria chemoprevention, the drive towards elimination of malaria in some settings and the availability of new antimalarial medicines, has renewed interest in the role that MDA can play in some settings. MDA should be viewed as a time-limited intervention with specific targets for when it should be discontinued, defined before implementation.

Currently, on the basis of the evidence, WHO recommends MDA:

- for interruption of transmission of falciparum malaria in areas approaching elimination,
- to reduce the risk for spread of multi-drug resistance in the Greater Mekong subregion,
- during malaria epidemics and
- in exceptional complex emergencies.

WHO recommends use of MDA for falciparum malaria, with two distinct, complementary objectives. The first is to reduce transmission of malaria, which is the primary aim of elimination and reduction of multi-drug resistance and is also relevant in malaria epidemics and complex emergencies. The objective is to quickly reduce the parasite biomass in a community and to prevent new infections for a certain period. Repeated rounds of MDA are given to remove parasites and prevent new infections in persons who were not reached in previous rounds. The expected result is a large reduction in transmission intensity. Synchronization of the intervention with high coverage of the entire population at risk is essential. In order quickly to reduce and potentially entirely interrupt transmission and avoid resurgence, several rounds are required, in combination with other malaria control tools and strategies such as effective vector control, access to prompt diagnosis and treatment and intensified surveillance.

The second objective of MDA for falciparum malaria is rapid reduction of morbidity and mortality. This is a primary aim when falciparum transmission results in high mortality rates, as in epidemics and complex emergencies when health systems are overwhelmed and unable to provide core malaria preventive and curative services. In these settings, MDA is used as an initial emergency measure; several rounds are implemented while access to case management and vector control are being put in place. It is important to identify the population at risk for severe malaria and death in order to define the target groups for MDA. These may be either an entire population or specific vulnerable groups who are at high risk for mortality because of lack of vector control and access to effective case management. High coverage of such target populations is more important than synchronization, as the primary aim is to reduce morbidity and mortality in the target population and not to reduce malaria transmission.

For MDA to be successful, high coverage and adherence of the target population (i.e. > 80%) must be ensured, which require a high level of community engagement and participation. Implementation strategies should therefore guarantee the highest level of participation possible. Door-to-door distribution is generally preferred to centralized distribution at a fixed site, and directly observed treatment (DOT), where feasible, is the best way to ensure adherence to treatment.



Implementing MDA for malaria is a complex, logistically challenging operation, which requires significant investments of resources (human, financial and logistic) as well as careful planning and organization. The intent of this manual is to provide technical and operational guidance on the practical aspects of organizing a successful MDA campaign for malaria. The main steps for efficient management are listed below.

Design phase

In this phase, the main strategies for MDA are established at national level:

- Obtain commitment from policy-makers, and identify agencies to support the ministry of health.
- Establish a task force or coordinating committee.
- Conduct a context analysis.
- Decide to implement MDA for falciparum malaria.
- Define target areas and target population.
- Choose the antimalarial medicine.
- Estimate the requirements for the medicine, and procure it.
- Determine the MDA strategy.
- Estimate the budget.

Planning and preparation phase

This phase involves planning the operational aspects of the framework defined at national level:

- Conduct micro-planning at province or district level according to the strategies defined by the national task force to guarantee an effective campaign by ensuring adequate distribution of supplies, training of staff, engagement of the community and proper management of resources. The micro-plan should include:
 - demographic information on the province or districts eligible for MDA;
 - information on the area (e.g. maps, infrastructure, location of health facilities, hard-to-reach areas);
 - timing of MDA in the district;
 - delivery strategies;
 - human resources (number required, number available) and training plan;
 - logistical information;
 - social mobilization and communications plan; and
 - pharmacovigilance plan.
- Ensure effective logistics, taking into consideration:
 - procurement, storage and distribution of antimalarial medication;
 - procurement, storage and distribution of other supplies necessary for MDA;
 - transport;
 - accessibility to the entire target population, including those in hard-to-reach areas;

- identification and preparation of distribution sites; and
- waste management.
- Plan human and financial resources:
 - number of teams required and composition,
 - training and
 - adequate payment of salaries and per diem.
- Plan community engagement and social mobilization by
 - defining the roles and responsibilities of all partners;
 - assessing communities to understand the characteristics and social dynamics of the target population in order to orient the social mobilization plan;
 - preparing clear, simple, precise, consistent messages about MDA for malaria;
 - engaging the mass media by building relationships with local media representatives and disseminating information through the different media;
 - preparing to address negative rumours that may arise during the campaign, which could affect participation; and
 - Involving community leaders and other influential people in planning, so they will feel ownership of the campaign and its success.

Implementation phase

The implementation phase involves the actual distribution of antimalarial treatment and includes:

- stock management: preparation of distribution kits with all the necessary materials ahead of time at the distribution point or peripheral health facility at which supplies are prepositioned;
- distribution of the antimalarial medicine itself, either door to door or at a centralized, fixed site;
- supervision, an essential component to ensure the quality of the campaign: at peripheral, district, regional and national levels;
- data collection: collection and reporting of information on the number of people who receive treatment at community level, adverse drug reactions (ADRs) and analysis and compilation of data at higher levels through a well-established pathway of information flow; and
- coordination of all actors to monitor activities, detect any difficulties or constraints, address them and react to unforeseen events.

Monitoring and evaluation

- intra-campaign monitoring system: a high-quality system for monitoring the campaign allows identification of constraints that require immediate action; can be done by monitors identified within the team or by independent monitors;
- estimate of distribution coverage: the proportion of the target population that has been reached by distribution;
- post-MDA survey: recommended, if feasible, after each round or at least at the end of the entire campaign to obtain more reliable information on coverage and to evaluate adherence to treatment, determine reasons for non-participation or non-adherence and evaluate the presentation of ADRs;



- monitoring consumption: daily monitoring of the number of treatments distributed and the number taken;
- pharmacovigilance: a vital component of an MDA, which should be planned to ensure training, detection, reporting, management of follow-up of adverse events and to promote and monitor adherence by both passive and active surveillance. This component is also essential to obtain and maintain good understanding and compliance of the population;
- monitoring drug resistance: one of the main concerns with regard to MDA is the emergence and spread of drug resistance; although there is no evidence that MDA of artemisinin-based combined therapy (ACT) at therapeutic doses is related to the emergence of resistance, monitoring of resistance should be an essential component of an MDA campaign;
- evaluation of impact: through routine surveillance and parasitological surveys to support a decision to stop; and
- reporting: after each round and at the end of the intervention, of the coverage achieved, challenges and difficulties faced and solutions found, lessons learnt, practices with good results, effective social mobilization activities, useful tools and the costs of the intervention.

In epidemics and complex emergencies, a minimum set of MDA monitoring and evaluation activities should be defined in order to document impact and for reporting.

Although these steps are common to all settings, MDA for the purposes of reducing transmission of malaria or its elimination, for containing resistance, in response to an epidemic or in the event of a complex emergency may differ in ways outlined below in the corresponding sections.

This manual is intended to provide general guidance. Some sections may not be relevant in all contexts and should be adapted to local circumstances (for instance, urban or rural settings). The manual also provides templates and examples from previous experience with MDA for malaria in various contexts that may be useful for developing training material or data collection. The majority of the tools are included in the annexes to this manual.

1. INTRODUCTION

1.1 BACKGROUND

Mass drug administration (MDA) has played a crucial role in the control and elimination of a number of prevalent neglected tropical diseases. The aim of the programmes has been to treat prevalent infection and to reduce transmission in the population simultaneously, hence decreasing the burden of the disease (1,2).

Since the 1970s, MDA was not recommended as an anti-malaria intervention because of concern about its efficacy, especially the sustainability of the results, the logistical feasibility and the risk for accelerating drug resistance (3–5). Recent progress in malaria control, including the use of others forms of preventive chemotherapy, such as intermittent preventive treatment of malaria in pregnancy and seasonal malaria chemoprevention, together with the drive towards elimination of malaria in some settings and the availability of new antimalarial medicines, have renewed interest in the role that MDA can play in some settings (3,4,6,7), for example as part of work to contain multi-drug resistance and eliminate malaria transmission in the Greater Mekong subregion (8,9) and in certain complex emergencies, such as the 2013–2016 outbreak of Ebola virus disease (EVD) in West Africa (9–12).

1.2 DEFINITIONS

Mass drug administration consists of the administration of a full therapeutic course of antimalarial medicine (irrespective of the presence of symptoms or infection) to every member of a defined population or person living in a defined geographical area (except for those for which the medicine is contraindicated) at approximately the same time and often at repeated intervals. (3,9).

In order for MDA to be successful, a very high proportion, generally **more than 80% of the targeted population** must be reached during the campaign, depending on the intensity of transmission and the exact objective of the campaign (4,6,9,13,14). This requires a **high level of community participation and engagement**. It is not enough to reach the majority of the population with distribution: coverage will be effective only if the number of people in the community who **correctly complete the full course** of antimalarial treatment is adequate. To achieve this, the population must accept the intervention and be willing to take the medicine as prescribed.

1.3 OBJECTIVE

The objective of malaria MDA is to provide therapeutic doses of antimalarial medicine to as large a proportion of the population as possible in order to cure all symptomatic and asymptomatic malaria infections at the time of the intervention and to prevent reinfection during the period of post-treatment prophylaxis.

MDA at high coverage rapidly reduces the prevalence and incidence of malaria in the short term. Once MDA is stopped, however, malaria endemicity will return to its original level if importation of malaria is not prevented, in the absence of high coverage with other interventions such as vector control, case management, surveillance and response. The risk of such a return and the rapidity with which it occurs depend on the size of the residual parasite reservoir in humans, the rate of importation of new infections and the capacity of the vectors to transmit malaria in the target area.



1.4 WHO RECOMMENDATIONS

On the basis of a recent review of the evidence (9) and the advice of the WHO Malaria Policy Advisory Committee, the current WHO recommendations for use of MDA, mass screening and treatment and focal screening and treatment for malaria (15) are listed below.

1. Use of MDA for the elimination of *P. falciparum* malaria can be considered in areas approaching interruption of transmission where there is good access to treatment, effective implementation of vector control and surveillance, and a minimal risk of re-introduction of infection.
2. Given the threat of multidrug resistance and the WHO call for malaria elimination in the Greater Mekong subregion (GMS), MDA may be considered as a component of accelerated malaria elimination efforts in areas of the GMS with good access to treatment, vector control and surveillance.
3. Use of Time-limited MDA to rapidly reduce malaria morbidity and mortality may be considered for epidemic control as part of the initial response, along with the urgent introduction of other interventions.
4. Use of Time-limited MDA to reduce malaria morbidity and mortality may be considered in complex emergencies, during exceptional circumstances when the health system is overwhelmed and unable to serve the affected communities.
5. In the absence of sufficient evidence, WHO does not recommend the use of MDA in situations other than for areas approaching elimination, epidemics, and complex emergencies, as specified above (see 1–4).
6. Mass primaquine prophylactic treatment, requiring pre-seasonal MDA with daily administration of primaquine for two weeks without G6PD testing, is not recommended for the interruption of vivax transmission.
7. Mass screening and treatment and focal screening and treatment for malaria are not recommended as interventions to interrupt malaria transmission.
8. Medicines used for MDA must be of proven efficacy in the implementation area and preferably have a long half-life. WHO recommends that a medicine different from that used for first-line treatment be used for MDA. Programmes should include monitoring of efficacy, safety and the potential emergence of resistance to the antimalarial medicines deployed for MDA.
9. WHO supports the need for more research on the optimum methods of implementing MDA programmes, promoting community participation and compliance with treatment, and evaluating their effectiveness. Modelling can help guide the optimum method of administering MDA in different epidemiological circumstances and predict its likely impact.

In line with the above recommendations, this manual addresses use of MDA only for the control and elimination of falciparum malaria.

2. ORGANIZATION AND IMPLEMENTATION OF MASS DRUG ADMINISTRATION

2.1 DESIGN PHASE (MACROPLANNING)

Once it has been decided that MDA will be conducted, macroplanning should be started. This initial design phase, done at national level, is important to ensure a successful campaign and should involve the ministry of health and other key stakeholders.

When MDA for malaria is done to impact on malaria transmission, the administration of antimalarial medicine must be done in such a way that all targeted individuals are treated in a synchronized manner and each round is completed in a very short time, generally not more than one week. In complex emergencies, when the main objective is rapid reduction of malaria morbidity and mortality, synchronous administration is less critical.

Steps of the design phase:

- Obtain commitment from policy-makers, and identify agencies to support the ministry of health.
- Establish a task force or coordinating committee.
- Conduct a context analysis.
- Decide to implement MDA for falciparum malaria.
- Define the target areas and target population.
- Choose the medicine.
- Estimate the requirements for the medicine and procure it.
- Determine the delivery strategy (including period of intervention and number of rounds).
- Estimate the budget.
- Define the criteria for stopping MDA.

As MDA targets every individual in a given population (except those with contraindications to the medicines used), it may be combined with other public health interventions, such as health education, deworming and distribution of long-lasting insecticide-treated nets; however, experience in combining multiple medicines or programmes is limited, and careful consideration should be given in advance.

2.1.1 Identify agencies to support the ministry of health

MDA for malaria is a logistically challenging intervention, which will require careful planning and significant resources in order to be successful. Therefore, partners that can provide technical, financial and operational support should be identified and included in planning from the initial stages. The partners may be national (national and local government, the private sector, nongovernmental organizations, other civil society organizations, the media, community leaders, religious leaders) or international (funding agencies, procurement agencies and international nongovernmental organizations). Mapping donors and implementing partners is critical to the success of MDA. All should be encouraged to work within the framework of the “three ones” – **one** plan, **one** coordination and **one** monitoring and evaluation – under the oversight of the task force or coordinating committee.



As MDA usually comprises multiple rounds for high coverage and, if the purpose is to interrupt transmission or elimination, may be repeated in subsequent years, it is therefore important to secure sustained support to ensure satisfactory completion of the intervention. Malaria services should be in place and supported in monitoring communities in the long term after the MDA has been completed.

2.1.2 Establish a task force or coordinating committee

A task force or coordinating committee, under the stewardship of the Ministry of Health, must be created with representation from national, regional and target district level to serve as an oversight body in charge of implementation of the MDA campaign and ensure adequate allocation of resources.

Composition

The committee may include representatives from:

- the national malaria control programme;
- other relevant entities of the ministry of health, for example medicines, community health, neglected tropical diseases or other programmes with experience in MDA;
- national research institutions;
- the national medicines regulatory authority;
- the national pharmacovigilance centre;
- national, regional and relevant district health authorities;
- technical personnel from relevant hospitals;
- administrative authorities;
- support agencies (the United Nation Children’s Fund, WHO, other United Nations agencies, nongovernmental organizations);
- other concerned ministries;
- local representatives of civil society; and
- the private sector.

A campaign will be successful only with close collaboration and coordination among partners. All of them should agree and, if possible, sign a formal agreement that describes the tasks and responsibilities of each. If MDA is used in an emergency, decisions will have to be made quickly. In order to avoid delay in trying to reach consensus among different agencies on any conflicting issues, a defined decision-making authority (normally the ministry of health) should be identified that will be responsible for taking rapid decisions if necessary.

Responsibilities of the committee

The committee will be responsible for:

- agree whether MDA is appropriate to reduce transmission and/or morbidity and mortality
- preparing strategic guidance for MDA implementation and preparing a plan of action;
- mobilizing the necessary human and financial resources;

- coordinating partners and sharing information;
- identifying the target population and target geographical areas (section 2.1.4);
- establishing the chronogram (section 2.1.10);
- preparing, reviewing, adapting and updating guidelines and training materials;
- developing data collection and monitoring tools (section 2.3.4);
- drawing up the social mobilization and community engagement plan (section 2.2.4);
- ensuring a functioning drug safety monitoring system (strengthening any existing pharmacovigilance body or establishing one) to guarantee effective detection, management and reporting of adverse events related to administration of the antimalarial medicine and access to consultation and hospitalization, including any necessary rescue medication, free of cost (section 3.4);
- establishing monitoring and evaluation, determining objectives and methods and defining indicators (section 3);
- ensuring comprehensive malaria control activities are implemented in the context of elimination: diagnosis and treatment, vector control and detection and investigation of all cases;
- planning additional malaria control activities in the context of complex emergencies, such as diagnosis and treatment, vector control and surveillance;
- establishing the criteria for termination of MDA; and
- ensuring an effective surveillance system to compile and analyse changes in malaria burden;

Responsibilities of the regional or district task force

- micro-planning (section 2.2) in the framework of the strategy defined by the national task force and
- coordinating and monitoring the operational aspects of the campaign.

Subcommittees could be set up within the task force at both national and district levels, including, for example:

- a technical committee;
- a committee for information, education, communication, social mobilization and community engagement;
- a human resources committee;
- a training committee;
- a logistics committee;
- and a monitoring and evaluation committee.



2.1.3 Conduct a context analysis

Planning an MDA requires a systematic context analysis and information on a number of aspects that may have major practical implications for execution of the campaign:

- malaria situation in the country and neighbouring countries:
 - major human malaria species present;
 - malaria endemicity or transmission intensity (high, moderate, low or epidemic prone);
 - peak malaria transmission season;
 - malaria prevalence, incidence of uncomplicated and severe malaria and mortality;
 - high-risk groups: by age, gender and occupation;
 - other malaria control activities that are being (or have been) used, in particular distribution of long lasting insecticidal nets, indoor residual spraying, larval source management;
 - availability and type of diagnostic tests available and used;
 - national treatment guidelines;
 - other chemoprevention activities, in particular seasonal malaria chemoprevention, intermittent preventive treatment of infants or pregnant women;
 - resistance to antimalarial medicines;
 - main sources of financing of malaria control activities and implementation; and
 - mapping of malaria partners;
- administrative information:
 - country borders and administrative divisions and
 - grey areas or undefined boundaries that might challenge implementation;
- mapping of administrative boundaries, cities, villages, location of health structures, main roads;
- demographic data, including age distribution of the population and identified marginalized groups;
- health care organization:
 - available health infrastructure: hospitals, health centres, health posts;
 - available health care staff (number and level of training); and
 - traditional health care providers;
- environmental factors: climate and seasons (rainy, dry), extreme events linked to climate change (floods, droughts);
- geography of the target areas and nature of the terrain;
- security
 - existence of armed conflict, ethnic, religious or social tension or clashes; and
 - civil unrest, demonstrations, corruption;
- challenges to the health system: public health emergencies and disease outbreaks;
- experience and lessons learnt from previous MDA campaigns for neglected tropical diseases or malaria;

- previous crises in communication and rumours about the safety of MDA for neglected tropical disease or vaccination campaigns and lessons learnt;
- important local events: national and religious holidays, market days, elections, planned demonstrations, food distribution, MDA for neglected tropical diseases or vaccination campaigns, which may result in poor participation;
- local perceptions and beliefs (see section 2.2.4);
- supply: national and local purchase and storage possibilities, formalities for importing medicines, registration status of antimalarial medicine eligible for MDA (section 2.2.2);
- communications system: e.g. existing networks (providers of mobile communications), availability of Internet; and
- population displacement due to security problems, seasonal migration or nomadic populations.

2.1.4 Determine the target population and geographical areas

A thorough analysis of the epidemiology of malaria and of the aim of MDA – for epidemic control, malaria elimination or in a complex emergency – should guide decisions on the target population and the geographical areas that will benefit from the campaign. The larger the target population, the more challenging is implementation and the more resources (human, financial, logistic) will be required, as MDA coverage in the target areas is the major determinant of impact.

The demographic data used to calculate the target population should be as accurate as possible. This may be difficult to obtain in certain developing countries. If feasible, data should be provided by official sources. Estimates of population numbers can be acquired from (Fig. 1):

- head counts (census) or household registration before MDA (unlikely to be feasible in the context of emergencies);
- a recent population census (if available);
- household surveys;
- administrative registration (if available);
- data from other recent mass distributions (such as of long-lasting insecticidal nets), mass vaccination campaigns or previous MDA in the same area; or
- household mapping done by indoor residual spraying teams in areas where there are strong malaria programmes.

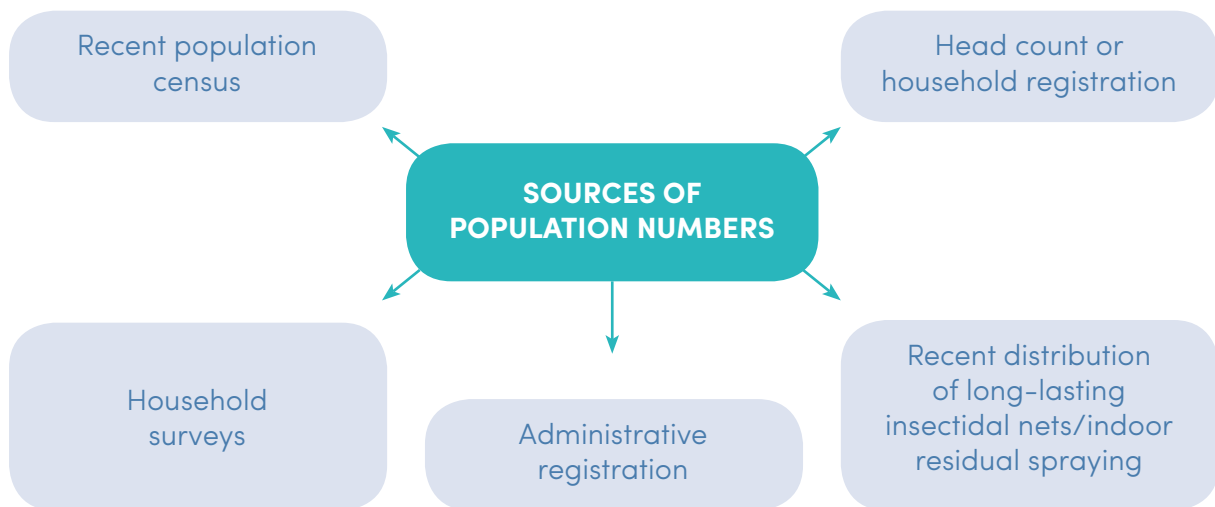
If no recent data are available to establish a realistic estimate, the annual population growth rate may be applied to the latest available population estimate. Population displacement into or out of the targeted geographical area should also be considered.

If several estimates are available, it is advisable to use the highest figures. Underestimation of the target population may result in errors in calculating orders and consequently a shortage of medicines, an inadequate number of distribution teams or inadequate time required to reach the entire target population. Such errors will ultimately compromise coverage and could also have a negative impact on the perception of the population that is excluded.



FIG. 1.

Sources of demographic information for calculating target population



After the first round of distribution is completed, the results may be used to recalculate the target population for subsequent rounds. The target population should be calculated by age group. If specific data on the age distribution in the country are not available, the standard age distribution for developing countries can be used (see Annex 1).

Certain population groups might have to be excluded from the campaign, depending on the medicine chosen for MDA:

- pregnant women in the first trimester: a decision to use pregnancy tests or self-reported pregnancy to exclude pregnant women should be guided by the health authorities and local context;
- infants < 6 months of age or weighing < 5 kg;
- people recently treated with the same medicine;
- people with known allergy to the medicine;
- severely ill people;
- people taking medication known to interact with the MDA medicine; and
- people with specific contraindications to the medicine used.

At the design phase, inclusion and exclusion criteria for participation in the MDA campaign should be clearly established. Estimation of the expected number of individuals who will be excluded from participation in the MDA may be useful for calculating orders, for planning purposes and for analysis of coverage.

The geographical area to be targeted must be defined on the basis of the size of the population in each zone or area, the population density and whether it is an urban or a rural setting.

Table 1 indicates differences in implementation between urban and rural settings.

TABLE 1.
Main differences in MDA in urban and rural settings

ELEMENT	URBAN SETTING	RURAL SETTING
Demographic data	<p>More difficult to estimate: mobile population, slum areas</p> <p>Difficult to determine administrative boundaries of neighbourhoods and other areas within cities</p> <p>Household census before MDA difficult</p>	<p>Estimates may be more reliable or more easily obtained</p> <p>Boundaries of villages are easily defined</p> <p>Easier to perform household census before MDA</p>
Logistic resources	<p>Fewer resources required, as population is densely distributed</p>	<p>More resources requires, as population is scattered, and more teams and time are required</p>
Accessibility	<p>More readily accessible</p> <p>Access may be difficult when there is insecurity</p>	<p>Access may be limited by distances, poor road conditions and effects of climate (rain)</p>
Human resources	<p>Easier to find qualified human resources</p> <p>Community health workers (CHW) and volunteers may be less well known to the population</p>	<p>Less qualified HR available</p> <p>CHW and volunteers are well known to and trusted by the population</p>
Community leaders	<p>More difficult to identify</p>	<p>Important role in micro-planning and social mobilization</p>
Door-to-door strategy	<p>Easier to miss households</p> <p>People less willing to allow access to their house, especially in higher socioeconomic strata</p> <p>People refuse to participate or are absent when they are in their workplace</p> <p>15–20 households can be visited per team per day (75–100 people)</p>	<p>Difficult to miss households</p> <p>People less suspicious and more welcoming of distribution teams</p> <p>People absent usually because of farming activities</p> <p>10–15 households can be visited per team per day (50–75 people)</p>
DOT strategy	<p>More difficult to achieve as people are less likely to be at home</p>	<p>May be easier to achieve</p>
Coverage	<p>More difficult to obtain high coverage</p>	<p>Higher coverage is easier to obtain</p>
Adherence to treatment	<p>Lower</p>	<p>Higher</p>
Rumours	<p>More quickly generated and disseminated</p> <p>More difficult to control</p>	<p>May be generated but easier to control and limit their dissemination</p>



2.1.5 Choose the antimalarial medicine

A number of elements should be considered when choosing which medicine to use.

- Efficacy: the 28-day cure rate for uncomplicated malaria patients should be > 90%.
- Safety profile: low frequency of medicine-related adverse effects, contraindications and consequences of inadvertent exposure of excluded individuals, such as pregnant women or HIV-positive patients on antiretroviral therapy. Even rare adverse events could occur in a considerable number of healthy recipients when the medicine is administered to a large population.
- Ease of administration: few tablets per dose and short duration of treatment.
- Reputation and acceptability: tolerance of the population to frequent even minor side-effects (e.g. nausea, weakness) and perception of risks and benefits, sometimes affected by rumours, may influence the acceptability of the medicines used in MDA.
- How to identify and exclude special populations groups for which at present there are no available options for malaria MDA: pregnant women in the 1st trimester and children weighing < 5 kg.
- Interactions: with other medicines used in the population, including other MDA interventions to the same population and antiretroviral agents used by HIV-positive patients.
- First-line ACT used in the country should preferably be avoided to limit the emergence of resistance and the impact on the supply for regular programmes and to avoid creating confusion and misconceptions in the population regarding the use of the medicine (prophylactic versus treatment) (9,10). Under certain circumstances, however, such as complex emergencies, the first-line treatment may be considered, as it will be well known by the population and the supply may be easier to guarantee.
- Availability of required quantities from suppliers at relatively short notice.
- Cost (available budget).

The best treatment is one that results in the greatest reduction in parasitaemia and transmissibility and the longest period of post-treatment prophylaxis, hence preventing reinfection. Long-acting ACT is the most suitable treatment in most contexts. The artemisinin component, which quickly clears asexual parasitaemia and also has gametocytocidal activity, has a short half-life, while the partner drugs provide different durations of post-treatment prophylaxis (see elimination half-life of partner drugs in Annex 2). The post-treatment prophylactic effect prevents acquisition of infection while the medicine remains in the bloodstream, protecting the individual as well as reducing transmission.

A complete (three-day) course of ACT should be administered; it is important to ensure adherence to the full regimen. Only co-formulated, fixed-dose combination tablets should be used in order to facilitate adherence and avoid resistance due to errors in administration of the medication. The five formulations of ACT currently recommended by WHO for the treatment of *P. falciparum* malaria are:

- artemether + lumefantrine
- artesunate + amodiaquine
- artesunate + mefloquine
- artesunate + sulfadoxine-pyrimethamine
- dihydroartemisinin + piperaquine

The ACTs listed above are recommended on the basis of their therapeutic efficacy, safety, impact on transmissibility and availability. Annex 2 gives the treatment doses and presentations of the ACT currently recommended by WHO. Research is currently under way on new compounds, and the above list may be updated in the near future.

Table 2 (on page 12) presents the characteristics of ACTs, which may assist in choosing a suitable antimalarial medicine for MDA.

The above comparisons indicate that dihydroartemisinin–piperaquine might be a suitable option for MDA, in view of its good efficacy, long post-treatment prophylaxis and good tolerability. It is not the first-line treatment for malaria in many countries, and resistance has been reported only in a few areas.

Special population groups that might have to be excluded from MDA

Pregnant women. No adverse effects on mothers or fetuses in the second and third trimesters of pregnancy have been reported, and ACT is considered safe for use in this population. As there are insufficient data on the safety of ACT in the first trimester of pregnancy, they should be avoided in women at this stage of pregnancy (16). Identification of women in the first trimester of pregnancy who are not yet visibly pregnant may be difficult in mass campaigns. The method for assessing pregnancy, through interview and/or testing, should be decided by the health authorities and based on the local context. Use of screening tests for pregnancy may be problematic, as many women or younger girls may not wish to disclose their pregnancy status, particularly in certain cultural settings. Before MDA, it is crucial to explain to the community the purpose of performing pregnancy tests and to assure them that they will be done confidentially. It is strongly recommended that interviews and pregnancy tests be performed by trained female community health workers in order to ensure privacy and discretion. A culturally sensitive approach is essential taking into consideration the values and perceptions of the communities.

Infants < 6 months of age or weighing < 5 kg. Although ACT is considered to be well tolerated by young infants, the operational difficulty of ensuring accurate dosing, because of the lack of infant formulations, the proper administration and retention of the treatment leads to the exclusion of young infants in MDA programmes.

Primaquine (8-aminoquinolines)

WHO recommends addition of a single low dose (0.25 mg/kg body weight) of primaquine (administered on the first day of the treatment with ACT) as a *P. falciparum* gametocytocide if the objective of MDA is to eliminate falciparum malaria or reduce the transmission of drug-resistant *P. falciparum* strains. Primaquine should, however, not be administered to infants < 6 months of age, pregnant women or women breastfeeding infants < 6 months of age.

Administration of the single low dose is safe and effective, even in G6PD-deficient individuals. In a recent review, WHO concluded that individuals with G6PD deficiency given a single low dose of primaquine are at very low risk of clinically significant haemolysis (17–19); therefore, it can be given without G6PD testing. The haemolytic effect of primaquine is dose-dependent and is observed mainly in individuals with G6PD deficiency given the 14-day regimen recommended for radical cure of *P. vivax* malaria.



TABLE 2.
Characteristics of WHO-recommended ACTs for choosing suitable antimalarial medicines for MDA

CHARACTERISTIC AND SELECTION CRITERIA	ARTEMETHER-LUMEFANTRINE (AL)	ARTESUNATE-AMODIAQUINE (AS-AQ)	ARTESUNATE-MEFLOQUINE (AS-MQ)	ARTESUNATE-SULFADOXINE PYRIMETHAMINE (AS-SP)	DIHYDROARTEMISININ-PIPERAQUINE (DHA-PPQ)
Efficacy	High in most settings	Variable, due to emerging resistance	High in most settings	Widespread resistance to SP	High in most settings
Half-life (days) (active drug)	1.4–11.4 (lumefantrine)	3.7–10 (desethylamodiaquine)	8.1–15.2 (mefloquine)	2.5–18.8 (SP)	13.5–28 (piperazine)
Safety	Safe and generally well tolerated	Generally well tolerated but associated with a higher incidence of gastrointestinal disturbances than other ACTs. AQ may prolong the QT interval and should not be given to people taking QT-prolonging medicines or who have congenital QT prolongation.*	Mefloquine induces nausea, vomiting and neuropsychiatric symptoms. Monthly treatment of healthy people is poorly tolerated.	SP is generally well tolerated but must not be used in patients with a history of hypersensitivity to sulfa drugs or in HIV-positive patients receiving cotrimoxazole, because of increased risk for adverse events.	Piperazine prolongs the QT interval and should not be given to people taking QT-prolonging medicines or who have congenital QT prolongation.*
Pregnancy	The risk-benefit ratio of administration of antimalarial medicines given to pregnant women as part of an MDA is different from that for malaria patients. As there are insufficient data on the safety of ACTs given during the first trimester of pregnancy, women in early pregnancy should be excluded for malaria MDA.				
Administration	Twice daily for 3 days, preferably with fatty foods (both likely to compromise adherence)	Once daily for 3 days (no requirements for food intake)	Once daily for 3 days (no requirements for food intake)	Once daily for 3 days (no requirements for food intake)	Once daily for 3 days on an empty stomach (ideally 3 h before or after meals, which is unlikely to be feasible in MDA)
Presentation	Fixed-dose combination; dispersible tablets and higher-dose tablets available for different age and weight groups	Fixed-dose combination	Fixed-dose combination	No fixed-dose combination available. Use of blister packs may result in distribution of loose AS tablets as monotherapy.	Fixed-dose combination
Commercial availability of prequalified product	Wide availability of prequalified original and generic products by many companies	Wide availability of prequalified original and generic products by many companies	Single prequalified product; limited production capacity	Single prequalified product; limited production capacity	Single prequalified product; limited production capacity

* Exclusion of patients with congenital QT prolongation would not be feasible in MDA, but people taking specific medicines might be identified before MDA.

2.1.6 Estimate the requirement for antimalarial medicine, and order it

Registration and authorization to import

As part of the drug selection criteria, especially for rapid deployment in emergency, it is necessary to consider the availability and requirements for registering the medicine, or obtaining a waiver, for its importation. Authorization to import the medicine and customs clearance should be agreed with the authorities beforehand to allow smooth, quick handling. These processes can take some time, especially if the medication is not licensed in the country.

Depending on the country's regulations, a post-shipment quality control test may be required for each batch of the medicine after it arrives in the country, and the necessary time should be included in planning.

Procurement

It is essential to ensure that the selected medicine meets international quality standards. The use of substandard, ineffective or unsafe medicines could be harmful for the population treated, affect the credibility of the campaign, increase the burden on the health care system and promote the spread of resistant strains if parasites are exposed to sub-therapeutic blood levels. Only prequalified medicines approved by WHO or by a stringent regulatory authority should be selected for MDA (20). The two main sources of relevant information are the WHO prequalification programme (21) and the Global Fund list (22). Consideration should be given to whether the supplier will be able to deliver the full required quantity at short notice, as not all suppliers have sufficiently large production capacity to deliver large quantities in a short time. Moreover, some manufacturers start production only once a purchase order has been received. These possible delays should be taken into consideration in planning procurement and in setting the dates of distribution.

Calculating the required quantity of medicine for different age groups

- Determine the size of the target population which will equal the total number of treatment courses needed, often in course-of-therapy packs, for each round.
- Calculate number of treatments per age group per round (according to the age-categories for which the selected ACT has specific presentations).
- Multiply the needs per round by the number of rounds that will be performed.
- Add a buffer stock of approximately 25% (depending on the reliability of demographic data) to cover wastage or underestimation of population.

See Annex 3 for examples of estimated orders of different presentations of artesunate–amodiaquine and dihydroartemisinin–piperaquine.

The calculation should also take into consideration the number of individuals expected to be excluded from coverage with MDA (e.g. pregnant women, infants, HIV patients, depending on the medicine selected for use).

2.1.7 Determine the delivery strategy

There are three possible distribution strategies:

- door-to-door distribution: the preferred strategy for high coverage, if logistically possible;
- centralized distribution at a fixed site; and



- a combination of door-to-door and centralized, fixed-site distribution:
 - centralized with door-to-door distribution for hard-to-reach groups or
 - door-to-door distribution followed by centralized distribution to follow up missed participants.

With combined strategies, care must be taken not to dose individuals repeatedly.

The choice of strategy will depend on logistic capacity, the objective of MDA and analysis of the local context, including security and any outbreak or other special circumstance.

DOT is the preferred delivery strategy for ensuring adherence and reducing the potential for mistakes in taking the medicine. Although DOT is more challenging operationally, it has been used successfully in very large-scale campaigns, including with multi-day drug regimens (4). As it may not be feasible to give all three doses of ACT by DOT, a health worker may administer the first dose and give the remaining tablets to the person or carer for days 2 and 3 of the intervention, with instructions on their administration. Because of the high risk of non-adherence to treatment on the two days following the administration of the first dose by DOT and consequent misuse of the medicine, adherence must be strongly emphasized both by the distributor and in the social mobilization campaign. An alternative that promotes and allows assessment of adherence to treatment and safety is giving the first and third doses by DOT. These different delivery options – full DOT, DOT on days 1 and 3 and DOT only on day 1 – have resource implications, which should be considered in planning the intervention.

If DOT for all three doses is not feasible, a strategy should be devised to encourage and monitor adherence. For example, CHWs could revisit the houses to which they have already distributed the medicine after finishing the distribution on days 2 and 3, or teams responsible for monitoring adherence could be appointed. Guaranteeing DOT in door-to-door strategies, when there is little likelihood that every member will be at home at the time of the health worker's visit, is laborious and complicated.

When MDA is planned as part of an elimination strategy and there is less time pressure than in an emergency intervention, a small-scale pilot MDA project is strongly encouraged to optimize the delivery strategy.

2.1.8 Determine the period of intervention

The best time for MDA depends on the setting and the aim of MDA (see Table 3).

MDA to reduce transmission and eliminate malaria

In an area with seasonal transmission, a campaign should be executed during the low-transmission season when the number of parasites is lowest, immediately before the start of the malaria transmission season (6,9,13,23). If MDA is conducted at the peak or during the main transmission season, there is less probability of influencing malaria transmission and the parasite prevalence will increase rapidly (13).

Timing should also take into consideration seasonal movements of the population in and out of the target area. Untreated people returning to an area after MDA constitute potential reservoirs and sources of re-infection.

The access of teams to certain rural and remote settings may also determine the period of MDA, as some areas may not be accessible during the rainy season.

MDA to help contain a malaria epidemic

MDA should be performed as soon as possible in order rapidly to reduce morbidity and mortality while outbreak containment measures are put in place.

MDA in complex emergencies

The period of the intervention will correspond to that of the highest risk for morbidity and mortality – the high malaria transmission season. If the burden of malaria is high all year round, MDA can be considered at any time of the year.

Certain complex public health emergencies, such as the 2014–2015 outbreak of Ebola virus disease (EVD), have major impacts on existing health care systems. During that epidemic, health care structures were overwhelmed, and access to regular health care was reduced, due to fewer functioning health facilities, loss of health care staff and fear among the population attending health structures and treatment centres of becoming contaminated with the Ebola virus. Laboratory testing was generally unavailable, and blood testing for malaria diagnosis was suspended. All these factors affected malaria case management, resulting in increased morbidity and mortality due to malaria. In addition, as the clinical presentation of malaria and EVD are similar, patients with malaria were suspected of having EVD, increasing the burden on EVD treatment units and also exposing non-EVD patients to nosocomial infection. Antimalarial MDA was provided in this context in an attempt to reduce malaria morbidity and mortality rapidly and thus to reduce the number of non-EVD patients presenting with fever to EVD treatment centres. Reduction of malaria transmission was not the objective of MDA in the context of the EVD epidemic.

2.1.9 Determine the number of rounds

Multiple rounds of MDA at regular intervals are recommended, although there is insufficient evidence at present to establish the optimal number and timing (3). Most MDA campaigns for falciparum malaria have consisted of two or three rounds at monthly intervals, and further research should be conducted to determine whether one or two rounds would be sufficient in certain situations (9). Special situations are listed in Table 3.

In *MDA to reduce transmission or eliminate malaria*, repeated rounds are necessary to clear parasites in the population. If some people remain untreated during a single round, with no additional intervention, the coverage will be partial and the impact in term of malaria transmission and burden will be lower. The aim of successive rounds is total coverage, reaching people who were initially missed and people who were treated in the previous rounds but may have been reinfected after MDA, reducing the probability of reinfesting mosquitoes. Multiple rounds may be required to obtain a major decrease in prevalence (6,8).

In *MDA as part of an epidemic response*, the number of rounds may depend on the epidemic curve (incidence rate and attack rate) and the expected duration of transmission.

In *MDA in complex emergencies*, the rounds should be repeated to cover the duration of the period of highest morbidity and mortality.



TABLE 3.

Main strategic differences between planning MDA for malaria elimination and for emergency response (epidemic or other complex emergencies)

	ELIMINATION SETTING (ELIMINATION AND CONTAINMENT OF MULTI-DRUG RESISTANCE)	EMERGENCY SETTING (EPIDEMIC, COMPLEX EMERGENCY)
Source of demographic data	Ideally, head count (census) or household registration before MDA	Head count or household registration less feasible Recent census (if available) Household surveys (if available) Other past mass distributions or MDA
Timetable for implementation	Usually allows sufficient time for planning and preparation	Short time for planning and preparation (≤ 1 month)
Urgency	+	+++
Coordination of partners and institutions	Required for successful campaign and easy to achieve	More challenging, as many actors may be involved, but essential to guarantee an effective campaign in a short time
Choice of medicines	First-line antimalarial agent should be avoided	First-line antimalarial agent may be considered
Timing in relation to malaria transmission for intervention	During the low transmission season, immediately before the start of the transmission season	During the peak of transmission (highest morbidity and mortality), depending on emergency context
Number of rounds per year	3	3 (but could be fewer)
Administration of antimalarial medicine	Must be synchronized in the target population in order to have an impact on transmission	Synchronous administration is important in epidemics in order to reduce transmission In other complex emergencies, the requirement for simultaneous medicine intake is less critical
Concomitant malaria control activities	Preconditions for using MDA for elimination are the availability of active case finding and surveillance, rapid testing and treatment of all cases of suspected malaria and intensified vector control	As the objective is to reduce malaria morbidity and mortality, MDA is deployed as an immediate response while other malaria control interventions, notably case management and vector control, are being put in place
Criteria for stopping MDA	Documentation of 0 indigenous cases (cases contracted locally with no evidence of importation or direct link to transmission from imported cases)	Reduction of malaria burden to a level that can be maintained with case management, vector control and routine surveillance, implemented in the same area

2.1.10 Establish a chronogram

A chronogram of activities (see Annex 4) will limit unexpected events, avoid forgetting things in the different planning phases and contribute to a successful intervention. Once distribution has begun, it might be difficult to correct a planning error. Poor planning, such as underestimating amounts or timelines for delivery of medicines, may lead to stock ruptures and will not only compromise the results of the campaign but also have a detrimental effect on the perception of the population.

The chronogram should show the evolution of all the tasks to be carried out during the phases of design, preparation, implementation and evaluation of the campaign. It will help to coordinate the many activities to be conducted at the same time and will indicate the role of each person.

The chronogram should contain:

- a list of tasks to be performed, including quantification and ordering of medicines and other supplies, training, distribution of materials, community mobilization and deployment of teams;
- a timeframe for the completion of each activity; and
- the name of the person responsible for each activity.

When deciding the actual dates on which distribution will take place, the activities and work schedules of the population and religious festivities and holidays should be considered to ensure high coverage.

2.1.11 Draw up a budget

The following items should be included in the estimated budget:

- MDA medicine;
- logistics:
 - registration fees;
 - international transport of medicine (e.g. international freight, insurance, customs clearance, importation fees or taxes, options for waivers);
 - pre- or post-shipment quality control testing (as applicable);
 - storage of antimalarial medicine and other logistics supplies;
 - transport: vehicles (cars, trucks, motorcycles, boats, bicycles), fuel;
- additional equipment and supplies for distribution: large-scale maps for overall planning and detailed maps to guide teams during the intervention, ropes, fencing, plastic sheeting, megaphones, chalk or other material for marking houses, rainwear (if MDA is conducted in the rainy season), backpacks, cups, other context-specific material (for biosafety for example) (See the comprehensive list of additional materials required for door-to-door and centralized fixed-site distribution in section 2.3.1);
- administrative material: e.g. cards, date stamp, daily tally sheets, summary sheets, supervisor sheets, attendance sheets, registration books, stationery;
- material for social mobilization and communication campaigns;
- staff salaries, per diem, food or transport allowances, identification material;



- materials for training and supervision;
- communication means: telephone, credit top-up for staff, radio;
- material for monitoring and evaluation: e.g. monitors, surveys, resistance monitoring; and
- material for drug safety monitoring.

It is important not only to estimate the cost of each budget line but also to identify the sources of funding. All partners and task forces should have the opportunity to review and provide suggestions to the budget plan, and the final version should be made available.

The exercise should estimate the total cost of the activity and a final analysis of the cost per person treated.

2.2 PLANNING AND PREPARATION

2.2.1 Micro-planning

Once the overall design of the campaign has been completed at national level, the next phase is to outline a micro-plan at local (regional, district or community) level for the strategies selected and according to national guidelines. The micro-plan should guarantee that the correct treatment and other materials are available in the right amounts, in the right places and at the right time to cover the entire targeted population. This will require distribution of supplies, training of staff, engagement of the community, well-coordinated distribution and proper management of resources.

Micro-planning is used to manage these details by calculating requirements on the basis of local needs, identifying what is available and requesting what is missing. Relevant partners should be involved in micro-planning, including:

- health centre staff,
- CHWs and community volunteers,
- local councils,
- community leaders or village representatives,
- religious leaders,
- the media,
- civil society organizations,
- women's groups,
- youth organizations,
- nongovernmental organizations,
- community organizations and
- schools and colleges.

The micro-plan should cover the following elements:

- demographic information:
 - total target population of the MDA-eligible district;
 - the numbers of communities, villages and neighbourhoods in the district;
 - the target population in each community, village and neighbourhood, with a breakdown by age group;
 - familiarity of the population with MDA for neglected tropical diseases;
 - proportions of people in urban and rural areas, in order to adapt logistic requirements (see Table 1 for details of differences in implementation of MDA in urban and rural contexts);
 - population movement;
 - depending on the size of the target population and context (emergency setting or elimination), household registration or census books of the target population that list all the households in a community, with an identification number and include the name, age and sex, village, head of household, contact details (if available) and resident status (permanent, temporary or visitor). This list can later be used during distribution to monitor coverage and to keep track of households that have been visited, missing people in a household and other details.
- information on the area:
 - maps showing main roads, villages, towns and neighbourhoods;
 - infrastructure in the area (e.g. availability of electricity, water, fuel);
 - location of health facilities and catchment areas;
 - areas or population that are difficult to reach because of geography, climate, lack of security or cultural reasons and suggested solutions for reaching them;
 - location at which medicines and other materials will be stored and then prepositioned for distribution; and
 - distances and travel times from the central area to each community, village or neighbourhood, health structures, storage sites and distribution sites (for centralized, fixed-site strategy) and road conditions;
- calendar timing of MDA in the district: ideally specifying days and times for certain streets or neighbourhoods, so that people can arrange to be at home;
- delivery strategies (centralized, fixed-site or door-to-door);
- human resources and training:
 - number of people expected to be covered by each team of distributors (whether door-to-door or centralized, fixed-site distribution);
 - number of teams required to cover all communities in the district;
 - number of teams per supervisor;
 - number of supervisors required per district;
 - human resources available in the district;
 - number of teams and supervisors that can be brought together per training session; and
 - number of days required to train staff.



- logistics information:
 - if centralized, fixed-site distribution is decided, the number and location of distribution sites, population per site, teams per site, etc.;
 - areas where staff may spend the night;
 - number of vehicles required to transport teams and supervisors and number of vehicles available locally;
 - amount of fuel required for transport;
 - amount of material required per team; and
 - material required for training;
- a social mobilization and communications plan; and
- a pharmacovigilance plan:
 - training of CHWs and community volunteers;
 - timing of active follow-up visits (days 3–7), depending on the safety profile of the medicine;
 - number and location of health facilities that will provide rescue treatment for any side-effects;
 - referral health facilities to manage severe adverse events;
 - distribution and completion of ADR report forms and narratives in health facilities; and
 - reporting and communication with stakeholders.

See Annex 5 for an example of a micro-plan used in Sierra Leone in 2014–2015 for antimalarial MDA during the outbreak of EVD.

2.2.2 Logistics

Supply and stock management

When the antimalarial medicine ordered for the MDA campaign is received in the country, it should be stored in a central warehouse or storage facility, which should be in an accessible location, with proper temperature and humidity conditions and well secured. Other essential material for the campaign (such as cups, sugar, mortars or pill crushers, stationery, soap, megaphones, rope, fencing) should be kept in the same location.

It is vital to estimate the volume of medicine (see Annex 3) and other logistics supplies beforehand to ensure enough storage capacity. The antimalarial medicine should be stocked by presentation (age-specific blisters), batch number and expiration date. A stock card should be prepared for each item in the store in order to monitor quantities and ensure traceability. The stock cards of the antimalarial medicine should include the international non-proprietary name (not brand names) and the dosage.

Antimalarial medicines and other logistic material will be distributed from central to district level, where intermediate centralized storage may be necessary, which should conform to the same indications.

Prepositioning of supplies

Antimalarial medicines and other logistic elements for distribution should be prepositioned in distribution points according to the micro-plan (e.g. peripheral health facilities) before MDA is launched. Therefore, the stock of each distribution point should be prepared in the central warehouse before delivery. Pre-printed order and delivery forms should be available. All movement of medication between individuals or organizations should be documented, and signed copies should be saved for future reference. See Annex 6 for a step-by-step procedure for prepositioning supplies.

Transport

Reliable transport is essential for all activities. The number and type of vehicles depend on:

- the strategy chosen (door-to-door or centralized, fixed-site distribution),
- the duration of the campaign,
- the number of distribution teams or distribution points (if centralized, fixed-site),
- the number of supervisors,
- whether the area is urban or rural,
- the social mobilization plan and
- the supply system.

Motorcycles, bicycles or boats may be required in some contexts.

During transport, medicines should be protected from weather such as rain and sunlight.

It is essential to check the local availability of vehicles and fuel. If cars are available, they should be evaluated for:

- type, size and condition;
- type of fuel and consumption; and
- the conditions of loan or rent (with or without driver, cost, insurance, etc.).

One person should be responsible for following up all issues related to transport, which is a potential target for fraud and/or theft.

Accessibility

The means for reaching all the eligible population should be assessed thoroughly, covering:

- the road network and the condition of roads,
- distances and travel times to the different locations and
- roads with limited or interrupted access during the rainy season and alternatives for reaching the populations.



“Difficult-to-reach” populations include not only those in remote areas with poor road access but also those isolated due to lack of security or social constraints. To ensure that these populations are covered, approaches such as assigning teams specifically to those areas or extending the duration of the campaign might be considered.

Distribution sites for centralized, fixed-site distribution

Sites should be chosen and prepared in advance. They should be selected in collaboration with local authorities and ideally have the following characteristics:

- easy access;
- be well-known to the population;
- possibility for creating a one-way flow of people (entry and exit points) to facilitate movement;
- large enough to work comfortably but not too vast that it is difficult to manage; and
- a large, shaded waiting area.

Possible locations could be schools, religious centres (churches, mosques, temples) or administrative buildings in urban areas; and, if there are no suitable buildings, open public spaces or temporary shelters, including tents, in rural areas.

If pregnancy testing of women of reproductive age is required before administration of the MDA medicine, the distribution site should also have bathrooms and private spaces where the test can be performed and the results communicated privately. **Sites should not be set up in health structures, so as to not disrupt normal activities.**

Waste management

Waste will be generated during an MDA campaign, and waste collection and disposal should be considered in the planning phase. The waste will consist almost entirely of soft waste, including packaging, disposable cups (if used) and pregnancy tests, if performed. For door-to-door distribution campaigns, waste may be handled at household or community level if adequate waste disposal systems exist. Otherwise, distributors should collect the waste and bring it back to the distribution point, where it should be incinerated. A decision to handle waste at community level or to centralize it at health facilities should be guided by the local context. For centralized, fixed-site distribution campaigns, waste can be disposed of at the distribution site or be transported to a central location (e.g. health facility).

2.2.3 Human resources

An MDA will require a significant number of dedicated staff. The number of teams required and their composition will depend on:

- the intended duration of the campaign,
- the distribution system (door-to-door or centralized, fixed-site),
- the target population,
- the target area and its accessibility,
- the expected performance of each team (number of people treated per day),

- data forms to be completed and
- addition of other interventions.

Team composition

As the antimalarial medicine is given orally, a large number of skilled health personnel will not be required. The number of qualified health workers taken from health structures should be minimized in order to disrupt the regular health activities as little as possible.

A census of all locally available human resources should be carried out during micro-planning. If a network of CHWs or volunteers is already present, they should ideally be engaged in delivering the medicine, as they understand the local environment, speak the local language and are familiar with and trusted by the population. If this is not the case or there are not enough staff according to the estimate, volunteers may be selected from e.g. civil society organizations, nongovernmental organizations, Red Cross or Red Crescent societies, youth associations, schools and nursing schools. If possible, the volunteers who serve as distributors should represent the demographics of the community. When selecting volunteers to distribute treatment or conduct social mobilization, local community leaders should be consulted, as they may help to identify people who are well known, recognized and respected by the community.

Each member of the team should have a job description, so that each clearly understands their role and responsibilities and those of the other members.

Distribution team

Door-to-door strategy. Teams should ideally be composed of two CHWs or volunteer distributors, if possible from the same village: one to provide information and administer the treatment and the other to record the necessary information on appropriate data collection tools. If pregnancy testing is planned, at least one of the two CHWs should be female.

Centralized, fixed-site distribution. Teams will consist of:

- 1 triage agent to check eligibility,
- 1 female worker to conduct pregnancy testing (if planned in the campaign),
- 2–3 registrars (if an MDA card is issued to each beneficiary or another registration system is used),
- 2–3 drug dispensers,
- 2–3 recorders to fill in a tally sheet (paired with drug dispenser),
- 1 health care worker to assess and manage adverse events,
- 1 sensitization or information officer,
- 1 cleaner and
- several crowd controllers and security personnel.



Supervision team

The supervisors should be health personnel, ideally from the same catchment area.

Door-to-door-strategy:

- Direct supervision of teams is difficult, and a large number of supervisors may be necessary to ensure quality.
- Each supervisor should be responsible for supervising no more than five teams in an area.

Centralized, fixed site distribution

- The number of supervisors will depend on the possibility of managing several sites.
- In urban areas, one supervisor might be able to visit up to three sites per day.
- In rural settings, one supervisor is likely to be able to visit only one or, at a maximum, two sites per day.

There should also be one logistics supervisor to manage the organization of sites, transport, supply, etc.

Estimated numbers of people treated per team per day (to be adapted to each setting):

Door-to-door strategy: The daily output of the teams will depend on the population density.

In urban areas, one team should be able to distribute medicine to a maximum of 75–100 people per day (average of 15–20 households of five people, visits lasting 15–20 min per household). In rural areas, where the population is more dispersed, one team should be able to distribute medicine to a maximum of 50–75 people (10–15 households) per day, in view of the time for transfer and communication to individual households. An approach used in several campaigns targeting large numbers of people has been to divide the population into small units and assign each to a distribution team (4).

Centralized, fixed-site strategy: One team should be able to distribute medicine to an estimated 400–500 people per day. As this strategy is likely to miss a higher proportion of the population than door-to-door distribution, special activities are required to mobilize and ensure the participation of the population.

The daily output of the teams will also depend on whether MDA cards are issued to participants or a registration book is completed, which is more time-consuming. It will also depend on the local context and previous experience in similar activities. Specific teams might be considered for distribution in schools, prisons, military camps and orphanages and perhaps for the main local companies, such as factories, mines and plantations.

Training

Training of staff is an essential component of the preparation phase. Everyone participating in MDA should take part in training sessions, including coordinators, supervisors, distributors, community mobilizers, logistics officers and any other staff. Training should be provided at national, regional, district and sub-district levels.

The plan should cover the objectives, which should be defined for each aspect; the length of training; the number of participants; the contents and methods; training materials and an evaluation (e.g. a pre- and post-test). Training should provide each team member and supervisor with the minimum information required to carry out their task properly. Training should be scheduled as close as possible to the date of implementation, ensuring, however, that all teams will have been trained by the time distribution begins.

All teams should be trained in a standardized way. If many partners are involved, they should all provide the same training to avoid any variations that could confuse trainees and lead to mistakes in drug delivery. Training should include:

- explaining MDA;
- goal of this MDA;
- where and when MDA will take place;
- the distribution strategy: door-to-door or centralized, fixed-site;
- treatment protocol and administration, including possible side-effects and contraindications;
- inclusion and exclusion criteria;
- performance of pregnancy tests and confidential communication of results (if applicable);
- DOT;
- team composition;
- roles and responsibilities of all team members;
- expected daily targets and overall coverage to be achieved;
- access to the medicine and other supplies;
- practicalities of distribution;
- reporting and management of side-effects and severe adverse events;
- information, education and communication and community engagement;
- dealing with rumours and any concerns or doubts in the target population;
- data collection tools: tally sheets, summary sheets, registration books, referral forms, ADR report forms;
- procedures for reporting;
- contingency plans for unforeseen events;
- management of stocks of medicines and other items;
- waste management;
- logistics;
- administrative issues (e.g. incentives and salaries);
- supervision and troubleshooting (for supervisors); and
- special measures (e.g. “no touch policy” or accidental exposure as in the outbreak of EVD).

Training plans should be adapted to the delivery strategy (door-to-door or centralized, fixed-site) to ensure that teams are well prepared. Job descriptions and any other reference documents or guidelines can be distributed during training after they have been discussed with the participants.



The methods used during training may include role-play, practical demonstrations, case studies and simulations, ideally with the material and equipment to be used, in order to cover all the details and correct any misunderstanding. Anticipating difficulties and responses in these scenarios is a fundamental part of training.

An efficient way to train many people quickly is cascade training, in which certain people are trained as trainers, and each in turn provides the same training course to others. More than one level of cascade should be avoided. Supervision of this training system is important to ensure that the information being passed down is accurate and the messages are not being changed as they are passed down.

Providing adequate training material, cooperative supervision and meticulous evaluation will guarantee that the skills in which distributors have been trained are applied appropriately.

Salaries and per diem

Large-scale MDA involves a significant number of people who are widely distributed geographically; they should be compensated accurately and in an opportune manner. Payment of salaries and /or incentives, per diem and food or transport allowances must be clearly discussed with all staff involved in distribution to avoid confusion and demotivation. CHWs and volunteers who are unhappy with their position and reward can jeopardize a campaign.

It is essential to determine how the money will be transported and managed at various levels to ensure that each person receives the correct pay, while guaranteeing transparency and avoiding opportunities for theft or corruption. The options for payment are decentralization to district authorities, through banks or "outsourcing" payments. Malaria control programmes may already have relevant experience during distribution of long-lasting insecticidal nets and indoor residual spraying campaigns. When many partners are involved, harmonization of payment to the teams is crucial. An innovative method is use of mobile phones, as used in Sierra Leone. Although some technical difficulties were faced because of the size of the transaction and the fact that it was the first time the phone company had handled such an operation, more than 6000 people were paid with this method in a timely, transparent manner, without having to gather for payment and removing the inherent security risks entailed in the movement of large sums of money (10).

2.2.4 Community engagement, social mobilization and communication

One of the main determinants of the success of MDA for malaria is ensuring high coverage of the target population and good adherence to the treatment, both of which depend on people's willingness to take the medicine (3,4,24). Many asymptomatic, healthy people will be asked to take a medication, potentially exposing them to adverse reactions. Ensuring compliance requires building mutual understanding and trust in the institutions implementing the campaign. Community engagement is a key factor in the success of MDA, in order to obtain the desired participation and uptake of medication.

Misconceptions within the eligible population about the treatment being administered, their risk for the disease, side-effects and the need for intervention even in people who are not ill contribute to non-participation (24,25). Effective communication and social mobilization are therefore critical to a successful MDA campaign (26). A communications plan should be developed and agreed upon by the ministry of health and other actors on strategies to reach target audiences.

The steps in preparing a communications plan are:

- Define the roles and responsibilities of each partner.
- Conduct a community assessment.
- Prepare clear, simple, precise, consistent messages about MDA for malaria.
- Engage the mass media.
- Engage the community.

Roles and responsibilities

At national level:

- Plan advocacy, communication, social mobilization and community engagement.
- Develop a tool for community assessment.
- Elaborate key messages.
- Coordinate activities.
- Hold advocacy meetings with stakeholders, including the private sector, at national level.
- Hold briefing with media houses, with an official launching, and identify role models who are willing to take the first dose publicly.
- Participate in panel discussions on national radio and television.
- Produce and air campaign spots in the main languages spoken in the target areas.
- Produce information, education and communication material, such as banners, flyers and fact sheets.
- Monitor the media during the campaign.

At district level:

- Carry out community assessment.
- Diffuse messages as widely as possible.
- Hold advocacy meetings with main stakeholders in the community, such as community leaders, administrative authorities, religious leaders, civil society groups and other associations or groups (women, young people) and traditional healers.
- Organize sessions to sensitize the private sector, schools, etc. about potential absenteeism of workers and students during the campaign.
- Identify potential participants in the community.
- Air jingles spots on local radio stations.
- Participate in panel discussions on local radio stations.
- Send vehicles with loudspeakers to make announcements about the MDA campaign to each village.



At community level:

- Hold discussions with chiefs and religious leaders in each village about the campaign.
- Disseminate messages through appropriate channels.
- Identify and train CHWs to carry out sensitization street to street and house to house in the days before distribution.
- Organize group sensitization sessions in communities with the participation of key people.
- Organize announcements by a town crier or a vehicle with a loudspeaker during the days before and during distribution.

Community assessment

Ideally, before planning MDA, a quick assessment and mapping of community groups in the targeted areas should be conducted to obtain qualitative information such as:

- social structures in the community;
- cultural specificities and customs;
- decisional power about health in families;
- role of traditional leaders, including community and religious leaders;
- behaviour considered acceptable for men and for women;
- health-seeking behaviour, including general knowledge about malaria;
- role of traditional medicine and traditional healers;
- acceptance of allopathic medicine;
- use of media;
- familiarity and understanding of posters, brochures and banners;
- literacy;
- languages spoken;
- perception of and willingness to participate in this type of intervention; and
- any concerns, which will be addressed during the sensitization campaign,

This assessment may avoid cultural misunderstandings that could threaten the success of the campaign. Useful lessons can be drawn from previous experience in MDA and similar activities.

Key messages about MDA for malaria

The messages to be prepared include:

- *What:* general information about malaria and about the campaign, emphasizing that malaria may be asymptomatic and that people can be infected without realizing it and highlighting the role of asymptomatic carriers in malaria transmission
- *Why:* purpose and benefits of treatment of people who do not feel sick and the importance of not saving the medicine for later use
- *When:* dates of the distribution and number of rounds
- *Where:* door-to-door or centralized, fixed sites
- *Who:* geographical area and eligibility criteria, with special emphasis on the need to exclude women in the first trimester of pregnancy and explaining the screening method which will be used (interview and/or pregnancy test) and assuring that it will be done confidentially.
- *How:* dosage and duration of treatment, adherence to treatment
- *Potential side-effects:* to avoid misconceptions and fear, possible side-effects should be described, with assurance of proper management of any that appear
- *Importance of continuation and reinforcement of other malaria preventive measures* (e.g. use of long-lasting insecticide-treated nets)
- *Context-specific messages:* might have to be prepared for each WHO recommendation for MDA during a malaria epidemic or a complex emergency such as an outbreak of EVD.

Engaging the mass media

Generally, spokespeople should be identified at the ministry of health and other credible, respected partners that are able to handle challenging interviews where awkward, inopportune questions are asked. Talking points should be prepared for speaking to and engaging with the media, avoiding the use of acronyms or scientific vocabulary that the public will not understand. Relationships should be built with local media representatives to ensure that they provide good news coverage; they should be contacted regularly, not only in response to a critical situation.

The campaign should be inaugurated with an opening ceremony covered by the media, in which influential people such as high-ranking administrative authorities and celebrities participate and take a dose of the medicine as an example to the rest of the community.

The methods that can be used to disseminate information and promote an MDA campaign include radio, television, newspapers, billboards, online news sites, social media, mobile phones and games.

Radio is widely available and very popular in rural areas in malaria-endemic countries and should be a priority for circulating information through radio spots, radio group discussions in which community members engage with campaign health officials and role-play of community members talking about the distribution in order to spread information about the purpose, location and timing of MDA and to discuss the benefits of participating and potential side-effects. Radio also allows listeners to call in and ask questions live. Radio spots (see Annex 7) can also be used. Radio can also be a powerful method, if the micro-planning is good, to disseminate information on the days and estimated times of visits of the distribution teams per street or neighbourhood or, in the case of centralized, fixed-site distribution, location and days. Television spots and phone-in programmes with key stakeholders can be influential.



Media messages should address any local concerns and doubts identified either in previous campaigns or during the evaluation phase. Personal testimony of people who have previously taken the medication is valuable.

Progress reports should be sent to the media throughout the campaign.

Countering negative rumours

Unfounded rumours or negative news may circulate, dissuading communities from participating in MDA. Random cases of unrelated severe illness or deaths in the community may be attributed to the antimalarial treatment and reduce the public's confidence in the campaign. A plan should be prepared in advance to suppress such rumours quickly in a prudent, neutral manner to reassure the population.

Distribution teams and supervisors should systematically collect information on rumours and on questions that are frequently asked at meetings with stakeholders and community groups and on radio and television programmes. Media reporting should be closely monitored to detect any negative coverage rapidly and react accordingly. If a relationship of trust is established with the media, they will be more likely to listen to all sides before reporting false information.

Community engagement

Community engagement at the early stages of planning is a key element of a successful MDA, so that they take ownership of the implementation and success of the campaign. The people to involve are:

- community leaders and other influential members,
- political leaders,
- local councillors and authorities,
- religious leaders (priests, imams, monks),
- schoolteachers,
- celebrities,
- other local groups (youth, women),
- village health workers or volunteers,
- health care staff (to respond to questions and concerns),
- traditional healers and
- private pharmacy owners and drug sellers (who could potentially interfere with the activity).

Cooperation with leaders and other influential members of the community is vital for good results, as their status as decision-makers makes them efficient promoters of the benefits of participating in the campaign; however, they must be well informed. Any negative opinion of the intervention will have a significant impact on the outcome. They can provide organizers with useful information on the best timing for the campaign, suggest people who should be included in sensitization sessions and how the sessions should be organized and identify potential distributors who are well known and respected by the community.

See Annex 8 for a list of discussion points that could be used in community meetings.

Social mobilization

Group social mobilization sessions in the community can be used to provide information, allow members of the community to ask questions and establish trust between the population and campaign staff. Priority should be given to hard-to-reach and underprivileged populations, and the programme should be adapted or intensified for those groups if necessary.

Other effective approaches are street theatre, music, art and other cultural activities.

Communication materials should be printed in the local languages and adapted to the literacy level of the community. They could include leaflets, posters, calendars, banners, armbands, t-shirts and caps. Megaphones or town criers could also be used.

Social mobilization activities should be held in religious centres, schools, cinemas and other recreational areas and places where people gather for other purposes, such as bus stops and hairdressers.

The activities in the different phases of social mobilization and communication are listed below.

Before the campaign:

- Ideally at least one month before administration of the medicine (depending on the setting and context): information about MDA, the benefits of the campaign, the importance of participation, etc.
- In the week before distribution: intensification of the sensitization campaign, with a focus on the practical aspects of starting the campaign and reminders to the population of days and location.

Before distribution is begun, several households should be visited to verify that people are aware of the dates and are willing to participate, so that last-minute adjustments can be made to sensitization activities.

During distribution:

- Social mobilization should focus on encouraging participation and promoting treatment adherence.
- Community mobilization messages should be adapted according to inputs from continuous observation by nonparticipants of people's reactions during MDA.

If MDA is conducted during the rainy season, villagers in rural areas might prefer not to participate in the campaign because of farming activities, either because they have to travel out of the eligible area to access their fields or because they fear that adverse effects might limit their capacity to work and thus provide for their families. This issue should be tackled in the communication plan to prevent or minimize refusal.

During distribution, the general perception and comments of the population towards the MDA campaign should be monitored to detect any problems, which should be addressed quickly. Community leaders could signal negative perceptions to the distribution teams or identify areas or neighbourhoods that have not been adequately covered.



After MDA is completed:

- Communities should be informed of the results by appropriate local platforms, such as radio, posters and CHWs.
- Teams or MDA representatives should remain in the target communities for some time after completion of MDA to identify and address rumours, concerns or other issues that could affect future rounds of MDA or other health interventions.

2.3 IMPLEMENTATION

The distribution of antimalarial medication should be started only if:

- the medicines and all other material (as outlined below) are in place;
- supervisory material is available (see section 2.3.3);
- teams are trained (see section 2.2.3);
- the logistics is ready (see section 2.2.2);
- the population has been informed of the details of the campaign (see section 2.2.4) and
- pharmacovigilance, including management of ADRs, is planned (see section 3.4).

2.3.1 Stock management

Distribution kits should be prepared ahead of time at the distribution point or at the peripheral health facility where supplies are prepositioned. Different kits should be prepared for distributors and supervisors. The quantities in the kits should be adequate for the number of people estimated to be reached per day.

Material required per distribution team

For door-to-door strategy (with DOT): Each team of distributors should be provided with the following materials at initiation of the campaign:

- backpacks (1 per CHW)
- mortar or pill crusher (for crushing tablets for infants)
- clipboards
- pens
- staff identification badge, t-shirt or armband
- hygiene material (soap)
- chalk to mark houses
- pad to note any concern
- printed information, education and communication material (drawings of age-specific dosages, adherence to treatment, expected adverse events, use of long-lasting insecticidal nets)

- umbrellas or clothing to protect against the rain

The rest of the material should be provided daily according to consumption and remaining stocks:

- the required number of treatment blisters to meet the daily target (including buffer stock)
- pregnancy test kits and urine containers if pregnancy tests are to be performed
- sugary solution for children if medicines with a bitter taste are used
- material for documentation: MDA cards, registration book, tally sheets, referral forms
- bags for waste collection

For centralized, fixed-site distribution: In addition to the above, the following should be considered:

- tables and chairs
- ropes or fence and poles
- shade net and/or plastic sheeting
- waste buckets
- drinking-water containers
- weighing scales
- disposable or reusable cups (if strict hygiene measures are in place)
- hygiene material (soap and other cleaning material)
- date stamp and ink
- identification panels for distribution site.

Material required for supervisors' kits

- clipboards and pens
- identification material, e.g. shirts, arm bands
- supervisory checklist, daily summary sheet, ADR report forms, referral forms
- pad to note any concerns.

For door-to-door distribution, the distribution teams should pick up the material at the distribution point or health facility at which it is prepositioned every morning, making sure that all the necessary supplies have been packed. At the end of the distribution day, the remaining stock should be brought back to the distribution point, where an inventory is made and recorded. All movement of antimalarial medicine and other supplies should be recorded by the person responsible for stock management. The kits should then be refilled in preparation for the following day.

If a team or a site requires further supplies because of shortages, the person responsible for logistics should be contacted to arrange transport, and the movement should be clearly documented to ensure accurate accountability. At the end of each round of distribution, the remaining stock of medicines and other items must be counted and reported at district, regional and national levels.



The supplies must be stored correctly for the next round, and antimalarial medicine and other supplies should be ordered for the next round.

After the last round is finalized, the remaining doses should be returned to district or national level, where appropriate storage should be ensured. Expiry dates should be checked. All other logistical material should be counted and also sent back to central level.

2.3.2 Distribution of antimalarial medicine

Actual distribution of medicine will depend on the distribution strategy chosen.

Door-to-door strategy

In urban areas, it may be difficult to ensure that all members of a household are present, waiting for the distribution team throughout the campaign. It is therefore advisable that each household be informed of the date and approximate time at which the distribution team will visit them.

The schedule of visits should be flexible in order to increase the chances of finding people at home. According to the context, visits should be made either early in the morning or in the evening for rural farmers or at midday for workers.

The distributors should follow the steps below when visiting each household (see also Annex 9):

- Greet the residents politely in their language, and introduce themselves.
- Ask for the head of the household, and verify whether all members of the household are present.
- Explain the objectives and provide information about the campaign. Distribution teams should have visual aids to transmit key messages translated into local languages.
- Obtain oral consent to participate.
- Check eligibility criteria. Anyone meeting any of the exclusion criteria (first trimester of pregnancy, infant < 6 months of age, known allergy to medicines, critically ill or presenting contraindications to the medication) should be told why they will not be given the treatment. Annex 10 presents an algorithm that could be used by CHWs to apply exclusion criteria.
- Individuals who are seriously ill, e.g. children with danger signs, should be excluded from MDA and be referred to the nearest health facility. All other ill patients should first receive the antimalarial treatment as part of the MDA and then be referred to a health facility for full assessment.
- A female health worker should speak to all women of reproductive age (15–49 years) alone, in a private setting to explain that ACT are not recommended in the first trimester of pregnancy and should also determine pregnancy status on the basis of personal history or a pregnancy test (see Annex 11 for an algorithm for determining pregnancy in women of reproductive age). Women who are visibly pregnant (assumed second or third trimester) may receive the medicine. If pregnancy is not apparent, the CHW may ask the following questions to help exclude a first trimester pregnancy:
 - Are you currently pregnant?
 - Do you think you could be pregnant?
 - Are you using any family planning method?

If the woman is unsure of her pregnancy status, a pregnancy test should be offered. If the test is positive, the woman is considered to be in the first trimester of pregnancy and should be excluded from the MDA.

Women who do not agree to have a pregnancy test should be warned of the risks and benefits of receiving ACT in the first trimester and given the choice to take it or refuse it.

Interviewing adolescent girls about pregnancy may pose an ethical issue, as parental consent might be required and is a subject of strong cultural sensitivity. Appropriate procedures should be defined in collaboration with the national reproductive health programme.

- Distribute a blister appropriate for the age category. The first dose should be administered under DOT. If a child is unable to swallow a tablet, the dispenser should teach the carer how to crush it and dissolve it in water and give the first dose to the child. If the medicine has a bitter taste, it may be given with a small amount of sugary solution to encourage the child to take it. If the dose is vomited (or rejected) within 30 min, the same dose should be repeated. The parent or guardian should request another dose from the CHW to complete the treatment.
- Teach the participants to take the remaining doses (on days 2 and 3), unless DOT is used for all doses. A laminated card with treatment doses should be used as a visual aid to support the explanations, and printed leaflets may be distributed (see Annex 12 for the leaflet used in MDA in Sierra Leone in 2014–2015).
- Clearly explain the importance of adherence to the full treatment course. Participants may be advised to keep the empty blister packs for assessment during post-distribution monitoring.
- Provide information on possible side-effects and what to do if they occur, including clear instructions for contacting the relevant services for assistance or queries.
- Ask the members of the household whether they have any questions, and allay any doubts they may have.
- Mark the tally sheet (see section 2.3.4 and Annex 13) after the person has taken the first dose, or fill in the registration book (see section 2.3.4 and Annex 14) and record the necessary information (e.g. name, age, gender, address, residency status, medication and dose given), including whether the entire household was covered or whether some members were missing, and specify the number missing.
- When the distribution team leaves the house, they may mark it with chalk as “complete” or “incomplete” according to the household members present; if no one was at home at the time of the visit, it should not be marked. If distribution in a household was incomplete or no one was at home, the team should revisit the house later in the day or the following day.

To simplify operations, the antimalarial medicine should also be given to people present in the community at the time of MDA who are not resident in the area (visitors), as long as they have no contraindication. In certain settings, such as in the context of elimination, they should be recorded separately, as they were not included in the calculation of coverage.

On days 2 and 3, once CHWs have finished dispensing daily treatment, they should return to households in their area in order to reinforce sensitization, promote treatment adherence and monitor ADRs.



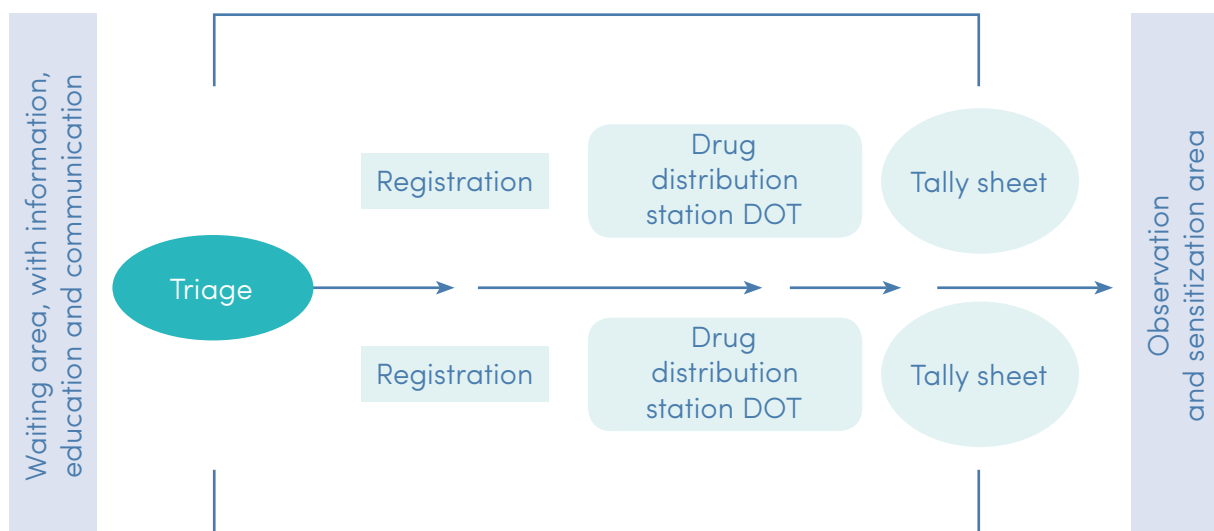
Centralized, fixed-site distribution

All distribution sites must have been identified in the planning stage and should be prepared the day before distribution begins. The site should be set up as follows (Fig. 2):

- Delimitation of the site with a rope or fence is recommended, and the site should be clearly identified.
- Waiting lines should be organized with rope or barrier tape and should be narrow enough for only one person to pass at a time. Crowd controllers may be necessary to ensure a smooth flow.
- Sensitization should be conducted in the waiting area.
- People should pass through an initial triage area, where their eligibility is verified. If they are considered eligible, they will continue through the circuit. If not, they will leave the area after the reasons for non-inclusion and registration have been explained.
- A private area should be identified for pregnancy screening of women of reproductive age as previously described.
- If it is decided that MDA cards will be handed to participants or a registration book completed (see section 2.3.4 and Annex 14), the next step will be registration. As this may be time-consuming, enough staff should be assigned to avoid bottlenecks and long waiting times.
- People will then proceed to the point where they will receive an appropriate blister for their weight or age category. The treatment distributors will administer the first dose under direct observation, and inform the recipients on how to take the medication on days 2 and 3 (unless DOT for all three doses is done).
- The tally sheet is completed for each participant after the medicine has been dispensed.
- An observation area may be set aside where people spend 30 min to ensure that they do not vomit and no severe adverse events or adverse events of special interest (see section 3.4.1) appear and where they will be sensitized about possible side-effects, what to do if they occur, administration of the remaining doses and the importance of adherence.
- All ill people attending the distribution should be referred to the nearest health facility.

FIG. 2.

Example of layout of a distribution site



2.3.3 Supervision

Supervision is important to ensure an effective, efficient, successful MDA campaign. Supervision should be conducted at various levels, with clearly defined communication lines between them. Supervisors should be appointed for the distribution teams and at the levels of districts, region or province (where applicable). National supervisors and coordinators should also be available.

Distribution team supervisor

The roles and responsibilities of the distribution team supervisor are:

Before distribution:

- Ensure proper reception and management of antimalarial medicine and other supplies at the peripheral health facility.
- Verify that all distributors are identified and trained and that local activities are organized and coordinated.
- Prepare the daily schedules of the distribution teams.

During distribution:

Morning

- Present the micro-plan and daily work plan for each distribution team.
- Check attendance, and find replacements in case of absence.
- Ensure that each team has the necessary medicine and material.
- Fill in part of the supervisory checklist.
- Deliver the daily data collection tools.

During distribution hours

- Visit distribution teams in their area of supervision, and provide technical support when needed.
- Randomly visit households, and interview members of communities that have already received the medicine to verify that they did receive the medicine and what they understood about taking the remaining doses.

End of the day

- Meet the distribution teams.
- Collect the remaining medicine and material (guarantee stock follow-up, and confirm consumption).
- Collect daily tally sheets and analyses.
- Compile data, fill in daily summary forms, and report to the district supervisor.
- Ask about any problem encountered during MDA or stock out, and report.
- Provide feedback to the teams, correct any mistakes, inform them of the progress of the campaign, and address any concerns.
- Prepare the medicines and material for the next day.
- Complete the supervisory checklist.
- Report to the district supervisor any difficulties or problems to be dealt with, rumours and refusal on the part of the population.



End of the campaign:

- Report the stock level.
- Return the remaining medicine and materials (to be arranged in collaboration with logistics department).
- Conduct debriefing with district supervisors and task force.

Supervisors should have the proper tools for their tasks, such as a supervisory checklist (see Annex 15).

District supervisor

The roles and responsibilities of the district team supervisor are to:

- supervise and support the distribution team supervisors;
- ensure that there is a team supervisor for all eligible geographical areas;
- visit peripheral health structures daily and react rapidly to questions and problems;
- ensure the daily presence of all teams;
- brief and debrief the team supervisors before and after each day's work, with particular attention to:
 - stock ruptures,
 - problems in data collection,
 - rumours circulating in the community,
 - insufficient information by distributors on correct administration of the medicine,
 - lack of motivation of health workers,
 - insufficient response to ADRs and
 - coverage of hard-to-reach populations;
- inform the district task force of any problem requiring immediate action that cannot be resolved locally;
- collect and compile the information on the daily summary sheets for the district;
- collect and review the team supervisors' checklists (may be done at the end of the campaign if there is not enough time during distribution) to identify any issues and lessons to be applied in subsequent rounds;
- present daily summaries to the district task force during evening debriefings and
- submit a written report to national supervisor.

Regional or provincial supervisor (if applicable)

The regional or provincial supervisor is responsible for supervising the district supervisors. He or she must follow up daily on the progress of the campaign and on any difficulties or problems, such as rumours. He or she must collect and analyse district summary findings and present a report to the national supervisor or coordinator.

National supervisor or coordinator

He or she oversees the regional or provincial supervisors, follows up the overall progress of the campaign and major difficulties, such as rumours, and analyses the summaries from regions or provinces before reporting to the national task force.

2.3.4 Data collection

Data collection is a vital component of an MDA in order to guarantee adequate follow-up of operations. The person responsible for collecting each type of data at each level and the mechanism of transfer from one level to another should be clearly defined (Table 4 and Fig. 3).

This is particularly important when several partners are involved in order to avoid duplication of data collection, missing data or mistakes in the destination of tallies or summary sheets.

FIG. 3.
Recommended information flow among levels

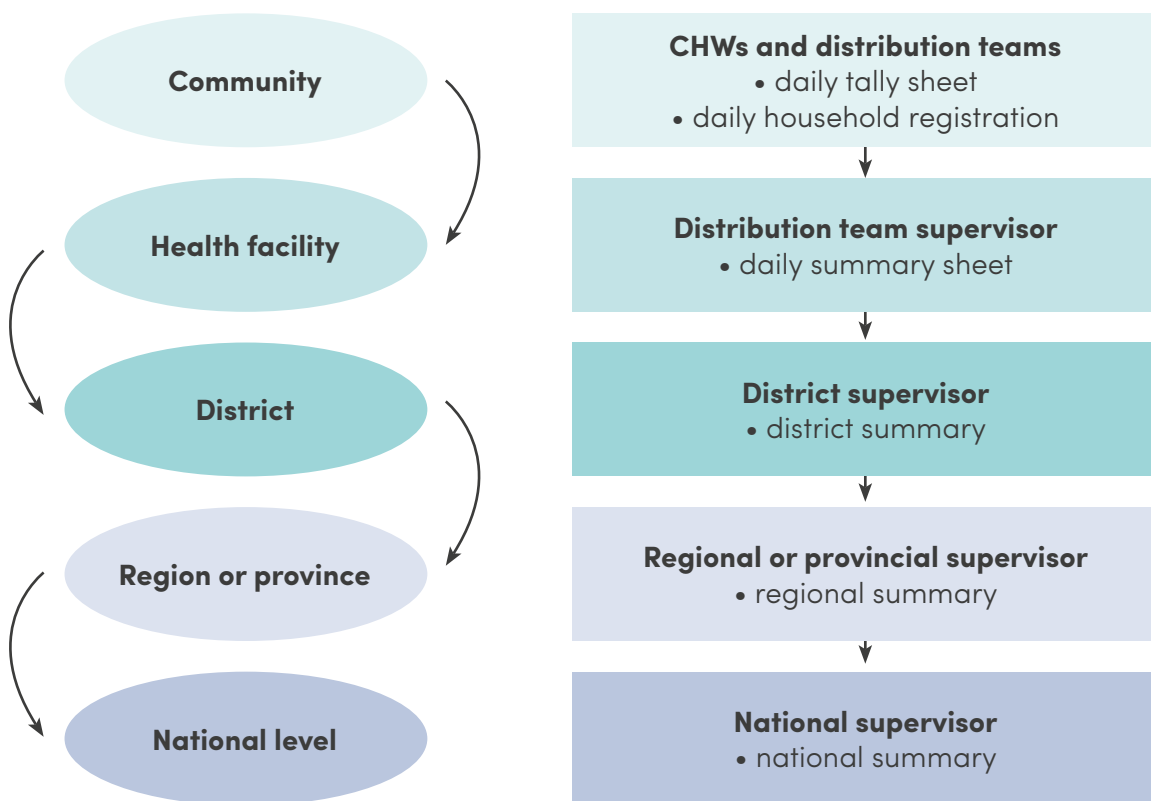


TABLE 4.
Data to be recorded at each level during door-to-door and centralized distribution

LEVEL	DISTRIBUTION STRATEGY	
	DOOR-TO-DOOR	CENTRALIZED, FIXED-SITE
Community	Census of people in each household or family (obtained before MDA, when feasible)	List of people in community, ideally with age and sex by family; otherwise, number of people per family
	Daily tally sheet with stock management (medicines, pregnancy tests and other consumables) per distribution team	Daily tally sheet with stock management (medicines, pregnancy tests and other consumables) per distribution site
	Record of each person, family treated, excluded, refused or not found (see household registration)	
	ADRs (name, age, sex, village, head of household, contact details, treatment taken, type of ADR, day of ADR) during days 2–7	ADR reporting (observations for 30 min while still at treatment centre)
	Referral form (in case of severe illness, ADR, pregnant woman who inadvertently received the treatment, other reasons)	
Health facility	Daily summary sheet and analysis of coverage by community in the health facility catchment area	
	ADR reporting (standard form)	
	Stock or logistics management form: antimalarial medication, pregnancy tests and other consumables in health facility stock	Stock or logistics management form: antimalarial medication, pregnancy tests and other consumables (stock may not always be prepositioned in health facility)
District	District summary sheet and analysis of coverage by health facility in the district	
	Compilation of ADR report forms from health facilities in the district	
	Stock or logistics management form: antimalarial medication, pregnancy tests and other consumables if district storage is used and when stock is returned from health facility	
Region or province	Regional or provincial summary sheet and analysis of coverage by districts in region or province	
	Compilation of ADR report forms from districts	
	Stock or logistics management form: antimalarial medication, pregnancy tests and other consumables if regional storage is used and/or when stock is returned from district level	
National	National total and analysis of coverage by region or province	
	Compilation of ADR report forms from regions or provinces	
	Stock or logistics management form: antimalarial medication, pregnancy tests and other consumables in national stock and when stock is returned from lower levels	

MDA cards

Provision of MDA cards (see Annex 16) to participants as proof that they received the treatment is optional and should be decided by the national task force during the design phase. If the task force decides that an MDA card will be provided, it should contain:

- last and first names of the drug recipient,
- age and sex,
- address,
- name and dose of the antimalarial medicine given and
- date of administration of the first dose if given by DOT or of each dose if all three doses are given by DOT.

Daily tally sheet

Tally sheets (see Annex 13) should be completed by each team on each day of distribution and handed to the supervisor at the end of the day. The following information should be recorded:

- date and place of distribution;
- distribution team identification;
- number of households visited;
- number of people who received the medicine, by age group (defined by age categories for the medicine) and by sex if considered relevant;
- individuals excluded and reason;
- residence status: resident or visitor (especially useful in elimination contexts, as all may not be included in the coverage calculation) and
- number of treatment blisters for each age category received at the start of the day and that remaining at the end of the day. The quantities of medicine consumed should correspond to the number of people treated, as recorded on the tally sheet. Discrepancies should be investigated to determine the cause, such as a mistake in distribution or theft.

Household or line list registration

Depending on the context (emergency or elimination), a household or line list registration (see Annex 14) may be used, with the following information collected:

- household identification;
- head of household;
- name of recipient;
- age;
- sex;
- village;
- contact details (if available);



- residency status (permanent resident, temporary resident, visitor);
- treatment taken;
- refusal, excluded (reason) or not found and
- observations.

Daily summary sheet

The distribution team supervisor should collect the completed tally sheets and compile the data corresponding to a certain geographical area (health centre catchment area, neighbourhood or village) on a daily summary form (see Annex 17). The tally sheets should be reviewed to ensure that they were properly completed and that the team is meeting the daily target. If not, the reason should be investigated (e.g. lack of sensitization, shortage of medicine, problems in recording). Feedback should be given to the teams on their performance and adjustments made, such as increasing the number of teams, changing the distribution site (in centralized distribution) or adapting mobilization.

Database

The data on the summary forms should be entered by a trained data manager into a centralized database at district, regional or national level (see Annex 18 for the database used in MDA in Sierra Leone), which will allow, at a later stage, a thorough analysis of the number of people treated, the number excluded, distribution coverage by age group and location and other information.

Referral form

A CHW who identifies a person who is ill, a pregnant woman in the first trimester who inadvertently took the antimalarial medicine or anyone presenting a potentially drug-related adverse reaction must fill in a referral form and refer the person to a health facility for proper management.

ADR form

If an individual presents symptoms that could be attributed to the antimalarial medication, an ADR form (see Annex 19) must be completed at a health facility or by a pharmacovigilance team. See section 3.4 for more details of pharmacovigilance and reporting of ADRs.

2.3.5 Coordination

During the days of distribution, daily meetings should be held at district and national levels, with the participation of all involved in the campaign in order to:

- monitor daily coverage; take action in problematic or challenging areas by targeting social mobilization or planning “catch up” distribution, ensure that hard-to-reach areas have been visited and guarantee that supplies have not run out;
- monitor stocks, and ensure an uninterrupted supply of the medicine;
- address any identified rumours or generalized refusal of the population;
- manage enquiries from the press;
- identify and correct any programme errors that could lead to failure of the campaign;
- share any pertinent information, and coordinate the activities of all partners; and
- mobilize the necessary resources in a coordinated way to respond to unforeseen events.

2.3.6 Treatment of malaria cases after mass drug administration

An individual treated during MDA who presents to a health facility with suspected malaria within 4–6 weeks should be assessed for possible malaria treatment failure or new infection. A positive result in a HRP2-based rapid diagnostic test cannot be relied upon, as a positive result may be obtained weeks after successful treatment due to persistent antigenaemia. Thus, microscopy should be used to confirm malaria. Ideally, health facilities should have antimalarial medicines in stock that are different from those used in the MDA. If microscopy confirms malaria, the health worker should enquire whether the patient adhered to the full course of treatment and if he or she vomited within the first 30 min of drug intake. If adherence was poor or the patient vomited, the same treatment used for MDA can be repeated. If adherence to treatment was good, a different antimalarial should be given, as possible treatment failure cannot be differentiated from a new infection in routine health care settings.



3. MONITORING AND EVALUATION

3.1 MONITORING SYSTEM

Given the complexity of the intervention, the limited number of times MDA can be done and the importance of the coverage of the intervention, monitoring is essential for success. The monitoring should be of high quality and not considered routine. Use of a monitoring system during a campaign allows full allocation of resources to operations and efficient implementation of activities while dedicating resources and capacity for a separate set of activities that allow identification in real time of constraints that require immediate action and will provide lessons for subsequent rounds of MDA.

The monitoring system should assess all phases of the campaign, by:

- interviewing distribution teams to determine the effectiveness of training;
- evaluating the logistics;
- interviewing community members to appraise the effectiveness of the social mobilization campaign;
- randomly visiting distribution teams to observe administration of the medication and counselling for adherence;
- assessing the quality of data collection;
- estimating actual coverage;
- evaluating adherence to treatment and rational drug use;
- monitoring drug safety and reporting adverse events;
- and monitoring impact.

Deployment of monitoring teams (internal or independent monitors) should be planned during the design phase in order to ensure adequate training in use of the monitoring tools.

3.2 ESTIMATE OF COVERAGE

After each round is completed, coverage is estimated to determine the proportion of people reached. Areas of low coverage might be identified to improve planning for the following round.

3.2.1 Distribution coverage

Distribution coverage can be defined as the proportion of the population who received the first dose of the treatment in that round, with the number of people who received the first dose as the numerator and the number of people in the target area as the denominator:

$$\text{Distribution coverage} = \frac{\text{number of people who received the first dose} \times 100}{\text{number of people targeted for treatment}}$$

The distribution coverage for each round and then the total MDA distribution coverage can be calculated. Additionally, distribution coverage should be estimated for each demographic group (age and sex) and geographical area, as applicable for campaign management. Although analysis by gender is not essential, it may be useful in settings where certain groups are likely to be underserved (e.g. girls). Such calculations do not, however, necessarily reflect the reality, because of difficulties in obtaining reliable demographic information, errors in data collection or inclusion of people from outside the target area in distribution.

The estimate of coverage will be more accurate if a household census was conducted before distribution, providing the denominator. In emergencies or other situations in which performing a census is not feasible, the recommended approach is to perform a coverage survey. As stated previously, the desirable coverage is > 80%. Coverage of < 80% may be due to poor participation, a shortage of supplies or an inadequate strategy for the campaign.

The reasons for not participating may be (12,26,27):

- population mobility (seasonal or routine movements of people out of the area targeted for MDA);
- unavailability or inability to participate at the time of MDA;
- difficulty in reaching the distribution site or a long waiting time (in case of centralized distribution);
- refusal to take the treatment because not sick;
- fear of ADRs;
- treatment considered to involve too many tablets and too long;
- rumours about the medicine;
- lack of engagement with community leaders and civil society in general;
- lack of trust in the campaign;
- misunderstanding and lack of adequate information about MDA;
- interference with other community events; and
- confusion between MDA for malaria and for other neglected tropical diseases, such as administration of praziquantel, which has side-effects that some people find difficult to tolerate.

Although MDA in rural settings is logistically more demanding, it may be more difficult to obtain high coverage in urban than in rural settings because of differences in the characteristics and dynamics of the population, including socioeconomic status, educational level, occupation and work schedules (28,29). Some studies have shown that populations with higher social status are more reluctant to participate in MDA (28). Young people and adults who drink alcohol regularly are unwilling to participate in MDA unless they are sick.



The reasons for non-adherence to full treatment include (12,27):

- not feeling sick,
- wanting to save the medicine for when they are sick,
- sharing the treatment with someone else,
- forgetting to take the tablets,
- fear of or appearance of side-effects,
- rumours about the side-effects of the medicine and
- inadequate health promotion or information on how to take the treatment correctly or on the importance of completing the full course.

3.2.2 Post-MDA campaign survey

A post-campaign survey is recommended when feasible, ideally within the week after distribution. The survey comprises visiting a representative sample of the population and systematically administering a questionnaire (see sample in Annex 20) to selected household members. The results can be used to estimate the coverage of the larger population with confidence intervals. Additional information about the campaign can also be collected during the survey.

Cluster sampling may be used. For information on performing a cluster survey of coverage, see Annex 4 of *Monitoring and epidemiological assessment of mass drug administration in the global programme to eliminate lymphatic filariasis: a manual for national elimination programmes* (30).

A post-distribution survey is useful to:

- estimate the coverage of the MDA,
- evaluate adherence to treatment (the number of people who completed the full course of antimalarial medicine),
- determine the reasons for non-participation,
- determine the reasons for non-adherence,
- estimate the proportion of people who experienced adverse events and
- evaluate the main adverse events reported.

3.3 MONITORING CONSUMPTION

The consumption of antimalarial medicine (number of treatments used) must be monitored daily and compared with the number of people reported to have been given the medication. Discrepancies between the two numbers should be investigated. They may be due to problems in recording the doses administered, errors in counting stocks, mistakes in administering the medicine or theft. Any of these problems must be suitably addressed with the teams.

A major problem that could arise as a consequence of lack of reliable demographic data is that the true population at a given site largely exceeds that expected. By monitoring consumption, an eventual stock rupture can be determined. A shortage of stock linked to reports from distribution teams or from community leaders that parts of the population have not yet received MDA may alert supervisors to this possibility. Under such circumstances, the buffer stock in central storage should be used. A more logistically demanding alternative would be to shift medication from over-stocked locations to under-stocked ones.

3.4 PHARMACOVIGILANCE

Even when medicines that have good safety and tolerability profiles are used, exposure of a large population may result in the appearance of rare side-effects in a number of cases. “Pharmacovigilance” is defined by WHO as the science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems (31). Pharmacovigilance in the context of MDA should be planned and implemented in collaboration with the national pharmacovigilance centre, which might be part of the national medicines regulatory authority or a research or academic institution. Pharmacovigilance systems depend on the performance and motivation of general health services staff, require centralized reporting lines and methods and skills for review, analysis and assessment of the causality of spontaneous reports of suspected drug reactions. The pharmacovigilance system should be organized at national, regional, district, state and municipal levels and also at health facilities and at community level in targeted populations.

The objectives of pharmacovigilance during MDA are to:

- detect unusually high rates of adverse events;
- ensure that coincidental events are not falsely associated with MDA;
- support timely detection and management of all adverse events (even those not attributed to MDA) to ensure the safety of the population;
- maintain confidence in the campaign by proper responses to community concerns about the safety of the medicine while increasing awareness about its benefits and risks;
- generate data about adverse events in certain populations such as asymptomatic carriers and healthy people for whom there may be no safety data, as these populations are not included in testing during development of medicines;
- promote and monitor adherence to the medicine by the targeted population, and detect reasons for non-compliance and the underlying causes, if possible;
- assess health systems preparedness to ensure drug safety monitoring at district and national levels by identifying appropriate responses in terms of knowledge of drug use (safety), training, knowledge and practice of pharmacovigilance; and
- evaluate the expected severity, frequency, distribution and outcome of ADRs in the targeted population in order to:
 - identify ADRs that are not listed in the product information leaflet or are not described in populations that were not tested during development of the medicine, such as asymptomatic carriers and healthy people;
 - assess the association between the ADR and the antimalarial;
 - provide a spectrum of the ADRs associated with use of the antimalarial in large populations; and
 - inform health care workers about patient counselling and monitoring in health facilities.



The expected ADRs and the toxicity of the medicine to be used in MDA should be well known to the organizing committee. Groups at all levels should be sensitized about potential ADRs, including the general public, CHWs (treatment distributors), supervisors and health care staff. Communities should be informed about expected mild reactions, with the information that they are usually transient and self-limiting or manageable by simple treatment; they should be encouraged to seek medical care for any rare or severe symptoms. Special attention should be paid to side-effects that may reduce tolerability and lead to poor adherence, such as nausea, vomiting, diarrhoea and abdominal discomfort. This could be done via television and radio, print media, social media, press conferences, community outreach and meetings.

3.4.1 Definitions

Adverse event: any untoward medical occurrence that may occur during treatment with a pharmaceutical product that is not necessarily causally associated with the treatment (32)

Adverse drug reaction (ADR): a response to a drug that is noxious and unintended and that occurs at doses normally used in humans for prophylaxis, diagnosis or therapy of disease or for modifying physiological function (32)

Serious adverse event or reaction: any untoward medical occurrence that, at any dose:

- results in death,
- is life threatening,
- requires hospitalization or prolongation of hospitalization,
- results in persistent or significant disability or incapacity or
- results in congenital abnormality or birth defect (33,34).

The detection of congenital abnormalities would require creation of a pregnancy registry, with enrolment and surveillance of all new pregnancies detected at antenatal care and in communities during the three months after MDA, and an evaluation to determine whether the women were pregnant at the time of exposure to the medicine. These women should be followed up to delivery to assess the outcome of the pregnancy, in terms of the health of both the foetus and infant and the mother (31). The cohort of pregnant women should be interviewed about any treatment with ACT or other medicines, with precise information on time of exposure and type of medicine and possible miscarriage, stillbirth or malformations. Analysis of data at the time of birth will allow a comparison of the frequency of miscarriage, stillbirth and congenital malformations among pregnant women who have inadvertently received various types of medicines during the first trimester.

Adverse event of special interest: refers to adverse events (serious or non-serious) of significant scientific, medical and public interest, for which monitoring and rapid communication to the provider and regulators could be appropriate (35). The event should be defined and reported if some safety signals were detected during the development of a drug that required additional monitoring.

3.4.2 Safety communication

Reports of ADRs and rumours about the safety of the drug can damage an MDA campaign and can also influence future MDAs or even use of the medicine in the country. A communication strategy should be prepared with the national pharmacovigilance centre before the MDA campaign, in line with internationally accepted best practices (36). Relations with the media and selected spokespersons should be defined well in advance, as timeliness and efficiency in crisis communication are essential to contain serious damage by circulating rumours.

Reported or perceived ADRs should be communicated appropriately to the media, with responses to any enquiries. Every serious adverse event must be properly recognized, reported and investigated. Once the assessment has been completed, the results of the investigation should be communicated to the community through appropriate media.

3.4.3 Surveillance of adverse drug reactions

Routine ADR surveillance must be enhanced during an MDA campaign to identify any potentially severe cases and to manage them adequately, to detect any programmatic errors and to reassure the general public. Rescue medicine and emergency medical material required for managing potential adverse reactions should be available in health facilities. Medication errors, such as in dose administration by distributors or in taking the medicine because of inadequate sensitization, could be at the origin of adverse events and should be duly reported.

In order to establish a functioning safety surveillance system, all personnel involved in an MDA campaign, especially health care staff, should be trained before the campaign on their roles and responsibilities, emphasizing prevention, early detection and management of adverse events and severe adverse events linked to the campaign as well as on the use of standard forms for reporting and the procedure to follow in case of a suspected severe ADR (notification system). Most countries have standard forms for documenting ADRs (see example in *Annex 19*). Forms for reporting suspected ADRs should be widely distributed, and clear guidance should be provided to health care staff and local health structures on completing the form.

Any reported severe ADR must be investigated to determine its relation with the antimalarial medicine, and all responses should be documented, including treatment. The reporting form adopted by the national pharmacovigilance centre should be used for spontaneous reporting. The forms may be adapted for active monitoring of a sample of the exposed population to include days of follow-up and findings of home visits. All reporting forms should record data on the patient, the suspected drug(s), concomitant medication, medical history, detailed description of the clinical course of the event(s), diagnosis, outcome, relevant laboratory or other diagnostic procedures and treatment received and any other information that supports causality (37).

Two pharmacovigilance methods may be used during MDAs.

- *Passive monitoring or spontaneous reporting:* reporting of a suspected adverse reaction by a health practitioner who becomes aware of a safety concern or by a patient. Thus, reporting is not solicited systematically. Nevertheless, both health workers and people receiving MDA should be advised (with clear contact details) to report any untoward event they may observe during or after MDA.
- *Active monitoring and reporting:* follow-up home visits by pharmacovigilance mobile teams or health workers trained in detecting adverse events after exposure to medicines for detection of short-term ADRs (during the week after administration) in every village, town or city in which the medicine was given. This is particularly important in settings where pharmacovigilance systems are weak and underreporting is significant. It involves active case finding and follow-up (“search, find, identify, refer and manage”). Any ADR detected should be reported to a health facility, and serious ADRs should be referred for further investigation and management.



To ensure effective communication and reporting of ADRs, a dedicated round-the-clock pharmacovigilance call centre or hotline could be set up to address queries from recipients of the medicine during the campaign. In countries where the national pharmacovigilance centre has an online electronic reporting system for ADRs, this can be used to enhance reporting if there is nationwide sensitization of consumers and health care professionals to the availability of the system.

All ADR reports collected during or after the campaign should be forwarded to the national pharmacovigilance centre for assessment and onward submission to the WHO global ADR database.

A health facility pharmacovigilance preparedness checklist (see example in Annex 21) could be used by pharmacovigilance monitors in communities to assess whether:

- there are adequate quantities of rescue medications to treat ADRs;
- staff are aware of the need for pharmacovigilance monitoring during the MDA;
- all staff have been apprised of and trained in pharmacovigilance monitoring and the adverse reactions to the antimalarial medicine that will be used in the campaign;
- staff were involved in advocacy and social mobilization before the campaign about the importance of adherence to the medicine; and
- ADR reporting forms are readily available at MDA sites, with clear forwarding instructions and contact details.

All health workers involved in the mass drug administration should be trained in pharmacovigilance (see example of training curriculum for drug dispensers in Annex 22).

3.5 MONITORING DRUG RESISTANCE

One of the main concerns about MDA is the emergence and spread of resistance to the drug, which spreads because resistant parasites develop greater transmission potential in the presence of the antimalarial medicine. In the past, indirect MDA (in which antimalarial drugs were added to salt distributed to the population) resulted in the development of resistance because of the use of sub-therapeutic doses of antimalarial medication (5,38).

MDA is likely to increase selection pressure on parasites. As antimalarial medicines with a long half-life are eliminated slowly from the body, during MDA, a large proportion of the population will have variable concentrations of the medicine in the blood over time. This increases the chances that malaria parasites will be exposed to sub-therapeutic concentrations of long-acting drugs (13,40,41). Thus, the post-treatment prophylactic effect, which is an important component of the protective and transmission-blocking effect of MDA, may also lead to selection pressure. Low adherence to treatment by a proportion of the population is expected to be higher in people with asymptomatic parasitaemia, which will also contribute to the exposure of malaria parasites to sub-therapeutic doses.

Until now, there has been no evidence that MDA of antimalarial medicines given at therapeutic doses results in the emergence of resistance (39). While the use of combination treatment reduces the possibility of selecting drug-resistant parasites (23), limited evidence on the impact of MDA on drug resistance indicates that resistance to antimalarial medicines should be monitored in areas where MDA is implemented on a large scale.

Several means for monitoring parasite (*P. falciparum*) resistance are relevant to MDA (42).

- *In vivo trials of therapeutic efficacy*: treatment of symptomatic patients with a standard dose of antimalarial medicine and measurement of the clinical (signs and symptoms) and parasitological (parasitaemia) efficacy of medicines and treatment outcome over a defined period. Although trials of therapeutic efficacy are considered the “gold standard” and are used in national malaria control programs to guide treatment policy, they are relatively complex to perform and not always easy to implement after MDA.
- *Detection of molecular drug resistance markers*: confirmation of genetic changes associated with resistance by molecular techniques. Serial detection of molecular markers is an accurate way of monitoring drug resistance and probably the preferred option. It has the advantage that samples can be easily obtained, transported and stored on filter paper, but it also requires expensive equipment. It can provide early evidence of resistance, particularly if pre-intervention data are available. Molecular markers of drug resistance are available for only a limited number of antimalarial medicines, notably chloroquine, amodiaquine, sulfadoxine + pyrimethamine, mefloquine, piperaquine and artemisinin. The correlation between molecular markers and the therapeutic efficacy of many antimalarials is imperfect and should be interpreted with caution.

In any scenario, at least one of the two methods should be available. Monitoring drug resistance will require collaboration with reference laboratories and with research entities at national or international level.

3.6 EVALUATING IMPACT

The ideal way of determining impact, especially when the objective is to reduce malaria transmission, is to monitor malaria prevalence by serial measurements of parasitaemia. The method used in pre- and post-MDA surveys should be the same in order to identify an effect.

A more practical way of evaluating the impact of MDA for malaria is monitoring routine surveillance data. The following indicators should be measured, ideally weekly, but at least at monthly:

- total number of consultations (outpatients),
- total number of suspected cases tested for malaria,
- total number of cases of confirmed malaria,
- total number of admissions of severe cases of malaria,
- number of deaths due to malaria,
- test positivity rate and
- total number of locally transmitted and imported malaria cases.

For epidemics and complex emergencies, a minimum set of MDA monitoring and evaluation activities should be defined in order to document impact and for reporting. Facilities that record confirmed malaria cases continuously can be identified in most settings, in order monitor over time the numbers of consultations and of cases of confirmed malaria in the target groups exposed to MDA and, if possible, in unexposed population groups.



These data should be compared before and after MDA in the targeted area; in a district covered by MDA and one that was not targeted, with a similar prevalence of malaria; and in the same district in a year in which MDA was carried out and one in which it was not. More detailed analyses could indicate the contributions of aspects such as environmental or demographic factors and concomitant interventions that also influence malaria trends.

When MDA is used as an emergency measure to reduce the burden of malaria and febrile illness rapidly, as was the case in the outbreak of EVD, the effectiveness in reducing both malaria morbidity and the number of febrile cases presenting to health services should be monitored (11,12).

In an epidemic, the effect of MDA is difficult to document, as the temporal change may be reflected simply as a plateau, a decrease or a reduction in the rate of increasing incidence in the epidemic curve.

4. REPORTING

After each round and at the end of the intervention, all partners at different levels (community, health facility, district, region, province, national) should gather for a debriefing and review to assess how the campaign went, share their experiences and impressions and make recommendations for the following rounds or future MDA. A report should be written in order to capitalize on the experience and identify lessons that could improve subsequent rounds or similar experiences. It should provide:

- the coverage achieved;
- the main findings, challenges and difficulties faced and successful or unsuccessful solutions;
- any practices that gave good results, including effective social mobilization activities;
- any useful tools that were developed ad hoc in response to unpredicted events, which could be incorporated into reference documents and included in training material;
- the final cost of the intervention (analysis per line item) and the cost per person treated;
- transparency and accountability for all resources used, including final inventories, destination of remaining treatment, return of logistic equipment, any donations made; and
- an evaluation of the whole operation.

The following is a proposed outline of the essential topics that should be covered in the report to be prepared at district level at the end of each MDA round:

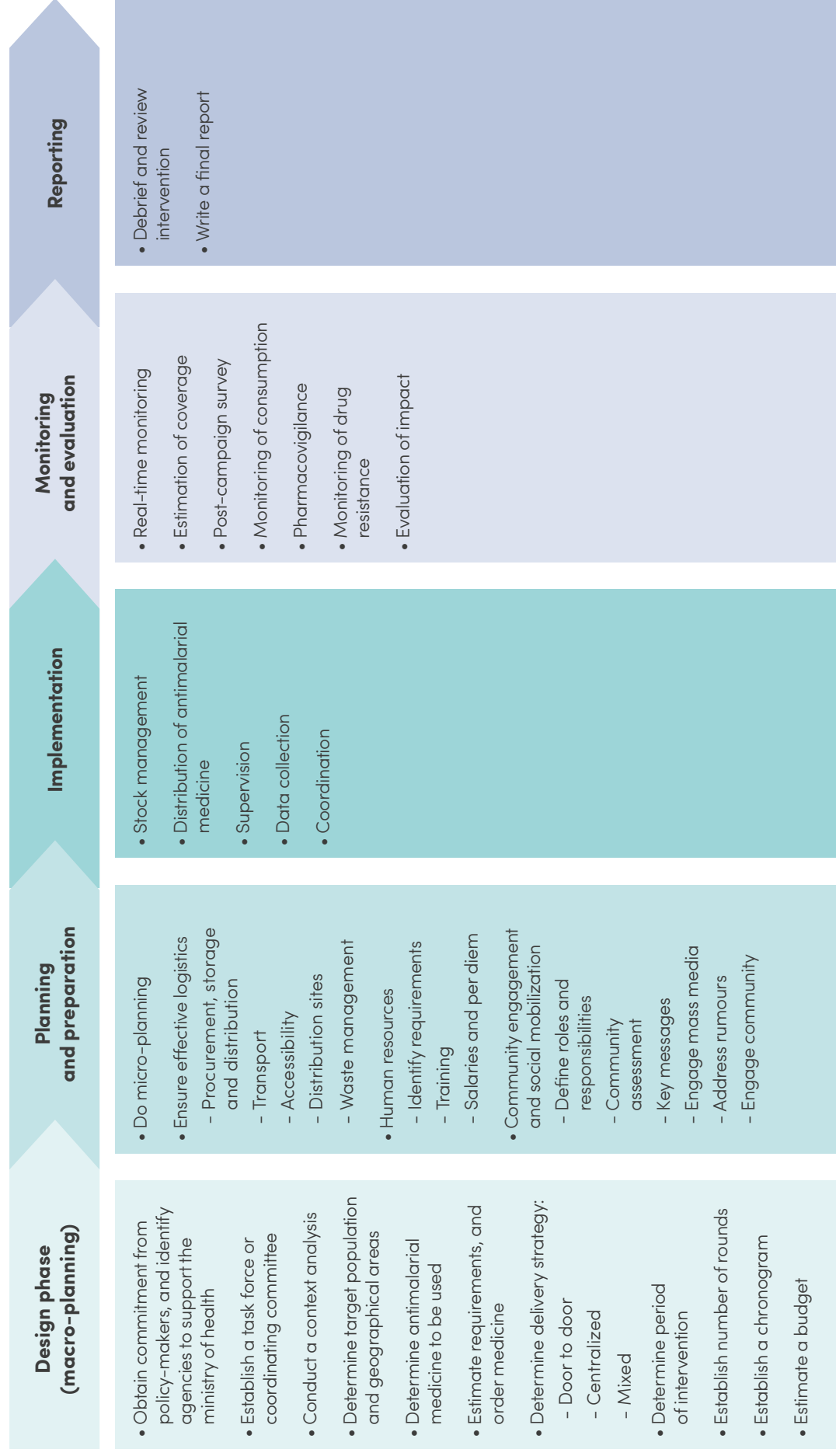
- Introduction and background
- Objectives
- Duration of campaign
- Geographical area of intervention and target population
- Treatment regimen
- Details of methods used during the campaign
 - Preparation and planning
 - o Recruitment and training of human resources
 - o Social mobilization and community engagement
 - o Logistics and supply
 - Distribution
 - o Strategy
 - o Practical aspects
 - o Supervision
 - o Data collection
 - o Results
 - Total number of people reached
 - Coverage
 - Excluded individuals and reasons for non-inclusion



- Monitoring: adverse events reported
- Other relevant aspects of monitoring
- Finance and administration, including breakdown per cost
- Strong points, difficulties, lessons learnt and recommendations
- Annexes

Another important component of reporting is feedback to the communities on the outcomes of the campaign and its impact. This will improve people's perception of the activity and build trust in the health authorities for future campaigns.

5. KEY STEPS IN A MASS DRUG ADMINISTRATION CAMPAIGN FOR MALARIA



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Annex 1

STANDARD DISTRIBUTION OF POPULATIONS IN A DEVELOPING COUNTRY

CHILDREN < 5 YEARS

AGE RANGE (MONTHS)	PERCENTAGE OF TOTAL POPULATION
0–11	4%
12–23	3%
24–35	3%
36–47	3%
48–59	3%
Total	16%

TOTAL POPULATION

AGE RANGE (YEARS)	PERCENTAGE OF TOTAL POPULATION
0–4	16%
5–14	27%
15–29	27%
30–44	16%
≥ 45	14%
Total	100%



Annex 2

AVAILABLE ARTEMISININ-BASED COMBINATION THERAPY: DOSING, FORMULATION AND PRESENTATION

DIHYDROARTEMISININ-PIPERAQUINE

WHO recommended doses

BODY WEIGHT (KG)	DOSES (MG) OF DIHYDROARTEMISININ AND PIPERAQUINE GIVEN DAILY FOR 3 DAYS
5 to < 8	20 + 160
8 to < 11	30 + 240
11 to < 17	40 + 320
17 to < 25	60 + 480
25 to < 36	80 + 640
36 to < 60	120 + 960
60 to < 80	160 + 1280
≥ 80	200 + 1600

Formulations available

Fixed-dose combination in:

- Paediatric tablets containing 20 mg dihydroartemisinin and 160 mg piperazine
- Tablets containing 40 mg dihydroartemisinin and 320 mg piperazine

Presentations

- Blister containing 3 tablets of 20 mg dihydroartemisinin and 160 mg piperazine
- Blister containing 3 tablets of 40 mg dihydroartemisinin and 320 mg piperazine
- Blister containing 6 tablets of 40 mg dihydroartemisinin and 320 mg piperazine
- Blister containing 9 tablets of 40 mg dihydroartemisinin and 320 mg piperazine
- Blister containing 12 tablets of 40 mg dihydroartemisinin and 320 mg piperazine

Remarks

- Dihydroartemisinin–piperaquine is an ideal candidate because of its efficacy and long post-treatment prophylactic effect. The elimination half-life of piperaquine is 13.5–28 days (1).
- Piperaquine prolongs the QT interval and should not be used with medication that prolongs the QT interval or in patients with congenital QT prolongation (1). Excluding patients with congenital QT prolongation would not be feasible in MDA. A single report of a sudden unexplained death considered potentially related to lethal cardiotoxicity has been reported among approximately 200 000 individuals closely followed up after treatment with this medicine (2–4).
- Dihydroartemisinin–piperaquine should ideally be administered to a person with an empty stomach, as high-fat meals accelerate the absorption of piperaquine, increasing the risk for a prolonged QT interval. Each dose should be taken at least 3 h after the last food intake; no food should be taken within 3 h of each dose.



ARTESUNATE–AMODIAQUINE

Recommended doses

BODY WEIGHT (KG)	AGE (APPROXIMATE)	DOSES (MG) OF ARTESUNATE + AMODIAQUINE DAILY FOR 3 DAYS
4.5 to < 9	2–11 months	25 + 67.5
9 to < 18	1–5 years	50 + 135
18 to < 36	6–13 years	100 + 270
≥ 36	≥ 14 years	200 + 540

Formulations available

Fixed-dose combination in tablets containing

- 25 mg artesunate and 67.5 mg amodiaquine
- 50 mg artesunate and 135 mg amodiaquine
- 100 mg artesunate and 270 mg amodiaquine

Presentations

- Blister containing 4.5 to < 9 kg (infant):
3 tablets of 25 mg artesunate and 67.5 mg amodiaquine
- Blister containing 9 to < 18 kg (toddler):
3 tablets of 50 mg artesunate and 135 mg amodiaquine
- Blister containing 18 to < 36 kg (child):
3 tablets of 100 mg artesunate and 270 mg amodiaquine
- Blister containing ≥ 36 kg (adult):
6 tablets of 100 mg artesunate and 270 mg amodiaquine

Remarks

- Artesunate–amodiaquine is associated with neutropenia, especially in HIV-positive patients on zidovudine and/or co-trimoxazole. Concomitant use of efavirenz may also increase the hepatotoxicity of amodiaquine (1).
- Although limited data is available, artesunate–amodiaquine is associated with QT interval prolongation similar to other antimalarial medicine such as quinine, chloroquine and dihydroartemisinin–piperaquine. No sudden unexplained death suggestive of cardiac arrhythmia at the doses used for malaria treatment have been reported despite widespread use suggesting that while cardiotoxicity may occur it is rare (4).
- Elimination half-life: 4–10 days (1).

ARTESUNATE–MEFLOQUINE

Recommended dose

BODY WEIGHT (KG)	AGE (APPROXIMATE)	DOSES (MG) OF ARTESUNATE + MEFLOQUINE GIVEN DAILY FOR 3 DAYS
5 to < 9	6 to 12 months	25 + 55
9 to < 18	1 to 6 years	50 + 110
18 to < 30	7 to 12 years	100 + 220
≥ 30	≥ 13 years	200 + 440

Formulations available

Fixed-dose combination in:

- Paediatric tablets containing 25 mg artesunate and 55 mg mefloquine hydrochloride (equivalent to 50 mg mefloquine base)
- Adult tablets containing 100 mg artesunate and 220 mg mefloquine hydrochloride (equivalent to 200 mg mefloquine base)

Presentations

- Strip of 3 tablets containing 25 mg artesunate and 55 mg mefloquine hydrochloride (equivalent to 50 mg mefloquine base)
- Strip of 6 tablets containing 25 mg artesunate and 55 mg mefloquine hydrochloride (equivalent to 50 mg mefloquine base)
- Strip of 3 tablets containing 100 mg artesunate and 220 mg mefloquine hydrochloride (equivalent to 200 mg mefloquine base)
- Strip of 6 tablets containing 100 mg artesunate and 220 mg mefloquine hydrochloride (equivalent to 200 mg mefloquine base)

Remarks

- Artesunate–mefloquine has a long post-treatment prophylactic effect (elimination half-life, ≤ 3 weeks) (1) but is associated with nausea, vomiting and neuropsychiatric symptoms, which may reduce its tolerability in MDA operations.



ARTEMETHER–LUMEFANTRINE

Recommended dose

BODY WEIGHT (KG)	AGE (APPROXIMATE)	DOSES (MG) OF ARTEMETHER + LUMEFANTRINE GIVEN TWICE DAILY FOR 3 DAYS
5 to < 15	2 to 59 months	20 + 120
15 to < 25	5 to 7 years	40 + 240
25 to < 35	8 to 12 years	60 + 360
≥ 35	≥ 13 years	80 + 480

Formulations available

- Dispersible or standard tablets containing 20 mg artemether and 120 mg lumefantrine
- Standard tablets containing 40 mg artemether and 120 mg lumefantrine

Presentation

- Blister containing 5 to < 15 kg:
6 tablets of 20 mg artemether and 120 mg lumefantrine
- Blister containing 15 to < 25 kg:
12 tablets of 20 mg artemether and 120 mg lumefantrine
- Blister containing 25 to < 35 kg:
18 tablets of 20 mg artemether and 120 mg lumefantrine
- Blister containing ≥ 35 kg:
24 tablets of 20 mg artemether and 120 mg lumefantrine

Remarks

Artemether–lumefantrine is probably not a suitable choice for MDA.

- It is currently used as first-line treatment in many countries.
- The complexity of the treatment regimen of two daily doses would probably compromise adherence.
- It has a short post-treatment prophylactic effect (elimination half-life, 3–6 days) (1).

ARTESUNATE + SULFADOXINE–PYRIMETHAMINE

Recommended dose

BODY WEIGHT (KG)	AGE (APPROXIMATE)	DOSE (MG) OF ARTESUNATE GIVEN DAILY FOR 3 DAYS	DOSES (MG) OF SULFADOXINE + PYRIMETHAMINE GIVEN AS A SINGLE DOSE ON DAY 1
5 to < 10	6–11 months	25	250 +12.5
10 to < 25	1–7 years	50	500 + 25
25 to < 50	8–14 years	100	1000 + 50
≥ 50	≥ 15 years	200	1500 + 75

Formulations available

Co-blister pack (there is no fixed-dose combination):

- Tablets containing 50 mg artesunate and fixed dose combination tablets containing 500 mg sulfadoxine and 25 mg pyrimethamine

Presentations

- Blister containing 3 tablets of 50 mg artesunate and 1 tablet of 500 mg sulfadoxine and 25 mg pyrimethamine
- Blister containing 6 tablets of 50 mg artesunate and 2 tablets of 500 mg sulfadoxine and 25 mg pyrimethamine

Remarks

- Artesunate–sulfadoxine + pyrimethamine does not exist as a fixed-dose combination, which would result in massive distribution of loose artesunate tablets, potentially leading to the emergence of resistance.
- Elimination half-life is 4.1–10.9 days for sulfadoxine and 2.5–18.8 days for pyrimethamine (1).
- The combination of sulfadoxine + pyrimethamine–amodiaquine, currently used in the Sahel as seasonal malaria chemoprevention, provides protection from reinfection for 28 days; however, it is available in a co-blister formulation and currently not recommended for individuals over 5 years of age. The efficacy of both sulfadoxine–pyrimethamine and amodiaquine is limited geographically due to increasing drug resistance to both medicines.
- Sulfadoxine + pyrimethamine should not be administered to people on co-trimoxazole (1).

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Annex 3

EXAMPLE OF CALCULATION OF ORDERS FOR ANTIMALARIAL MEDICINE

EXAMPLE OF CALCULATION FOR ARTESUNATE–AMODIAQUINE

Artesunate–amodiaquine comes in fixed-dose combination tablets, packed in age-appropriate blisters, in four presentations:

Dosage based on body weight or age

BODY WEIGHT (KG)	APPROXIMATE AGE GROUP	BLISTER PRESENTATION	DOSAGE
4.5 to < 9 kg	2–11 months	25 mg/67.5 mg tablets in blisters of 3 tablets	1 per day for 3 days
9 to < 18 kg	1–5 years	50 mg/135 mg tablets in blisters of 3 tablets	1 per day for 3 days
18 to < 36	6–13 years	100 mg artesunate + 270 mg amodiaquine in blisters of 3 tablets	1 per day for 3 days
≥ 36	≥14 years	100 mg artesunate + 270 mg amodiaquine in blisters of 6 tablets	2 per day for 3 days

Total population: 100 000

Age distribution (from standard age distribution for developing countries in Annex 1):

- 2–11 months ≈ 4% (0–11 months = 4%)
- 1–5 years = 12%
- 6–13 years ≈ 27% (5–14 years = 27%)
- ≥ 14 years ≈ 57% (≥ 15 years = 57%)

Target population by age group

	BREAKDOWN BY AGE GROUP (ACCORDING TO BLISTER PRESENTATION)			
	2–11 MONTHS	12–59 MONTHS	5–13 YEARS	≥ 14 YEARS
Percentage of total population	100 000 x 0.04	100 000 x 0.12	100 000 x 0.27	100 000 x 0.57
Total population per age group	4000	12 000	27 000	57 000

Estimate of number of treatments (= number of blisters) per presentation and volume requirement

	6–11 MONTHS	12–59 MONTHS	5–13 YEARS	≥ 14 YEARS	TOTAL
For one round	4 000	12 000	27 000	57 000	100 000
For three rounds	12 000	36 000	81 000	171 000	300 000
25% buffer stock	3 000	9 000	20 250	42 750	75 000
Total number of treatments	15 000	45 000	101 250	213 750	375 000
Estimated volume per treatment (in dm ³)	0.02	0.03	0.04	0.04	
Total estimated volume (in dm ³)	300	1 350	4 050	8 550	14 250

Example of calculation for dihydroartemisinin–piperaquine

Dihydroartemisinin–piperaquine is available as fixed-dose combinations in tablets containing 40 mg dihydroartemisinin and 320 mg piperaquine and in paediatric tablets containing 20 mg dihydroartemisinin and 160 mg piperaquine.

WHO dose recommendations based on weight

BODY WEIGHT (ESTIMATED AGE)	DAILY DOSE FOR 3 DAYS	TABLET STRENGTH AND NUMBER OF TABLETS PER DOSE
5 to < 8 kg (2–11 months)	20 + 160	1 x 20 mg/160 mg tablet
8 to < 11 kg (12–23 months)	30 + 240	1½ x 20 mg/160 mg tablet
11 to < 17 kg (2–4 years)	40 + 320	1 x 40 mg/320 mg tablet
17 to < 25 kg (5–7 years)	60 + 480	1½ x 40 mg/320 mg tablet
25 to < 36 kg (8–13 years)	80 + 640	2 x 40 mg/320 mg tablet
36 to < 60 kg (≥ 14 years)	120 + 960	3 x 40 mg/320 mg tablet
60 to < 80 kg (adults)	160 + 1280	4 x 40 mg/320 mg tablet
≥ 80 kg (adults)	200 + 1600	5 x 40 mg/320 mg tablet



Total population: 100 000

Age distribution (based on standard age distribution for developing countries, Annex 1):

- 2–11 months \approx 4% (0–11 months = 4%)
- 12–23 months = 3%
- 2–4 years \approx 9% (2–5 years)
- 5–7 years \approx 9% (5–14 years = 27%)
- 8–13 years \approx 18% (5–14 years = 27%)
- \geq 14 years \approx 57% (\geq 15 years = 57%)

Target population by age group

	AGE GROUP					
	2–11 MONTHS	12–23 MONTHS	2–4 YEARS	5–7 YEARS	8–13 YEARS	\geq 14 YEARS
Percentage of total population	100 000 x 0.04	100 000 x 0.03	100 000 x 0.09	100 000 x 0.09	100 000 x 0.18	100 000 x 0.57
Total population per age group	4 000	3 000	9 000	9 000	18 000	57 000

Estimation of number of treatments (= number of blisters) per presentation

REQUIREMENT	DIHYDROARTEMISININ/PIPERAQUINE				
	20 mg/160mg 3-tablet blister	40 mg/320mg 3-tablet blister	40 mg/320mg 6-tablet blister	40 mg/320mg 9-tablet blister	40 mg/320mg 12-tablet blister
1 round	10 000	9 000	27 000	28 500	28 500
3 rounds	30 000	27 000	81 000	85 500	85 500
25% buffer stock	7 500	6 750	20 250	21 375	21 375
Total number of treatments	37 500	33 750	101 250	106 875	106 875

The total number ordered should be adjusted according to existing stocks, back orders and other sources.

Annex 4

EXAMPLE OF A CHRONOGRAM FOR MASS DRUG ADMINISTRATION FOR MALARIA (DISTRIBUTION AT 8 WEEKS)

DATES	Person Responsible	W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12	W13	W14	W15	W16	END
Coordination																		
Creation of task force and define composition																		
Definition of roles, tasks																		
Creation of subcommittees																		
Task force meeting																		
Sub-committees Meeting (National & District Levels)																		
Written proposal of MDA																		
Development of tools																		
Conduct micro planning at district level																		
Final report																		
Antimalarial medicines																		
Estimation of medicine needs																		
Check existing stocks/backorders																		
Make medicine order																		
Reception of medicine order																		
Stock management (cards, batch number)																		
Distribution of medicines to district level																		
Pre-positioning of medicines in peripheral health structures																		
Other equipment (team supplies, data collection tools, stationary, etc.)																		
Estimation of needs																		
Evaluation of available resources																		
Order necessary supplies																		
Reception of supplies																		
Preparation of kits																		



DATES	Person Responsible	W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12	W13	W14	W15	W16	END
Distribution of supplies to district level																		
Pre-positioning of logistic kits in peripheral health structures																		
Logistics and transport																		
Evaluation of needs																		
Evaluation of available resources																		
Order or rental of vehicles																		
Verification and maintenance																		
Vehicle movement plan and follow up																		
Human resources																		
Estimation of needs																		
Evaluation of available personnel																		
Selection and recruitment of missing personnel																		
Identification of allocation of staff and supervisors																		
Create training materials																		
Training of trainers																		
Training of supervisors																		
Training of distribution teams																		
Training of monitors																		
Training of drug safety monitoring teams																		
Supervision																		
Salaries/perdiem																		
Social mobilisation																		
Develop communication plan																		
Develop key messages																		
Produce and distribute IEC material																		
Advocacy meetings with Key actors at national level																		
Advocacy meetings with Key actors at district level																		

DATES	Person Responsible	W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12	W13	W14	W15	W16	END
Sensitization of specific groups at community level (traditional leaders, authorities, religious leaders, women's groups, etc.)																		
House to house and street to street sensitization																		
Town criers/ megaphones																		
Press briefing																		
Monitoring of press																		
Planning of radio and TV programming/ads																		
Participation in radio/ TV panel discussions																		
Elaboration of radio jingles																		
Airing of radio jingles																		
Distribution sites (for centralised strategies only)																		
Define number of sites needed																		
Identification of sites																		
Visit sites																		
Organisation of sites for distribution (tables, chairs, etc.)																		
Antimalarial medicine distribution																		
Preparation of materials																		
Checking of materials																		
Supply during campaign																		
Implementation of round one																		
Implementation of round 2																		
Implementation of round 3																		
Supervision activities																		
Monitoring and evaluation																		
Data analysis																		
Evaluation of distribution coverage																		
Monitoring activities																		
Post distribution survey																		



Annex 5

EXAMPLE OF MICRO-PLANNING IN URBAN WESTERN AREA, SIERRA LEONE

Description of each health facility, target population per facility, age distribution and volume of material

No.	Name of facility	Type of facility	Owner	Locality	Chiefdom/zone	Population DHMT	POPULATION PER AGE GROUP (+ 5% BUFFER STOCK)		BOX VOLUME (M ³)			TOTAL VOLUME				
							Population DHMT + 5% buffer stock	6-11 m (2%)	12-59 m (13.7%)	5-13 y (28%)	> 14 y (54.5%)		6-11 m (2%)	12-59 m (13.7%)	5-13 y (28%)	> 14 y (54.5%)
12	Wellington	CHC	Govt	Wellington	1	34 460	36 183	724	4957	10 131	19 720	0.09	0.60	1.22	3.16	5.05
14	Koya Town	CHC	Govt	Upper Wellington	1	10 093	10 598	212	1452	2967	5776	0.03	0.18	0.36	0.93	1.48
16	Allen Town	CHC	Govt	Allen Town	1	40 161	42 169	843	5777	11 807	22 982	0.10	0.69	1.42	3.68	5.89
19	Al-Khatib Clinic	CHC	Mission	Calaba Town	1	10 599	11 129	223	1525	3116	6065	0.03	0.18	0.37	0.97	1.56
20	Calaba Town	CHC	Govt	Calaba Town	1	20 330	21 347	427	2924	5977	11 634	0.05	0.35	0.72	1.86	2.98
22	St Luke's Clinic	Clinic	Mission	Congo Water	1	17 951	18 849	377	2582	5278	10 272	0.05	0.31	0.63	1.64	2.63
34	AWAKE	Clinic	Private	Allen Town	1	4230	4442	89	608	1244	2421	0.01	0.07	0.15	0.39	0.62
41	Family Home Movement	CHP	Mission	Upper Calaba Town	1	8603	9033	181	1238	2529	4923	0.02	0.15	0.30	0.79	1.26
44	Ad-Bangs Quarry	MCHP	Govt	Blackhall Road	1	10 039	10 541	211	1444	2951	5745	0.03	0.17	0.36	0.92	1.48
48	Mayemie	MCHP	Govt	Mayemie	1	12 602	13 232	265	1813	3705	7211	0.03	0.22	0.45	1.15	1.85
54	Philip Street	MCHP	Private	Philip Street	1	10 615	11 146	223	1527	3121	6074	0.03	0.18	0.38	0.97	1.56
63	Old Dominion (EPI)	Hospital	Private	Upper Mellon Wellington	1	10 300	10 815	216	1482	3028	5894	0.03	0.18	0.36	0.94	1.51
Total Western Area						1141 738	1 198 625	23 976	164 239	335 671	653 360	13 067	89 510	182 941	356 081	7 122

DHMT, district health management team; m= months; y= years; CHC, community health centre; CHP, community health post; MCHP, maternal and child health post; EPI, Expanded Programme on Immunization

Numbers of teams and human resources required per catchment area

Zone	Name of facility	No.	Total population per facility	Families per facility	Families/day	Families/day/team	No. of teams required	No. of teams proposed	No. of team supervisors	No. of CHWs proposed	
1	Wellington	12	34 460	6892	1723	30	57.4	57	11	114	
	Koya Town	14	10 093	2019	505	30	16.8	17	3	34	
	Allen Town/UPAL	16	40 161	8032	2008	30	66.9	67	13	134	
	Al-Kharab Clinic	19	10 599	2120	530	30	17.7	18	3	36	
	Calaba Town CHC	20	20 330	4066	1017	30	33.9	34	7	68	
	St Luke's Clinic	22	17 951	3590	898	30	29.9	30	6	60	
	AWAKE Clinic	34	4 230	846	212	30	7.1	7	1	14	
	Family Home Movement	41	8 603	1721	430	30	14.3	14	3	28	
	Ad-Bangs Quarry	44	10 039	2008	502	30	16.7	17	8	34	
	Mayemie	48	12 602	2520	630	30	21.0	21		42	
	Philip Street	54	10 615	2123	531	30	17.7	18	7	36	
	Old Dominion (EPI)	63	10 300	2060	515	30	17.2	17		34	
	Holy Mary Clinic	64	5 800	1160	290	30	9.7	10	2	20	
	Total Zone 1						30		327	64	654



Requirements for material per team per catchment area

No. of PHUs	Number of teams	Clipboard (1/team)	Pen (4/team)	Backpack (2/team)	Badge holder (2/team)	Badge for CHW (2/team)	Daily tally sheet (2/team and day)	Daily summary form (1/day / 20 teams)	Supervision check-list (1/day / 20 teams)	CHW briefing note (2/supervisor)	Lentil on AS-AQ, 2 faces, laminated	Stock card (20/PHU)	Badge for supervisor (1/supervisor)	Badge holder for supervisor	Folder with clip (2 per supervisor)	A5 notebook (2/ supervisor)	Blue pen (2/ supervisor)	A5 thin notebook (2/team)	Permanent marker (1/5 teams)	Plastic pocket for SC (1/supervisor)	Dosage (1/family)	Plastic folder for documents (1/team)	Plastic bag (1/team)	
12	57	57	228	114	114	114	456	12	12	4	114	20	11	11	22	22	22	114	12	11	30	57	57	
14	17	17	68	34	34	136	136	4	4	2	34	20	3	3	6	6	6	34	4	3	30	17	17	
16	67	67	268	134	134	536	536	14	14	4	134	20	13	13	26	26	26	134	14	13	30	67	67	
19	18	18	72	36	36	144	144	4	4	2	36	20	3	3	6	6	6	36	4	3	30	18	18	
20	34	34	136	68	68	272	272	7	7	4	68	20	7	7	14	14	14	68	7	7	30	34	34	
22	30	30	80	40	40	160	160	4	4	2	40	20	6	6	12	12	12	40	4	6	30	20	20	
34	7	7	28	14	14	56	56	2	2	2	14	20	1	1	2	2	2	14	2	1	30	7	7	
41	14	14	56	28	28	112	112	4	4	2	28	20	3	3	6	6	6	28	3	3	30	14	14	
44	17	17	68	34	34	136	136	4	4	2	34	20	8	8	16	16	16	34	4	8	30	17	17	
48	21	21	84	42	42	168	168	5	5	2	42	20	8	8	16	16	16	42	5	8	30	21	21	
54	18	18	72	36	36	144	144	4	4	2	36	20	7	7	14	14	14	36	4	7	30	18	18	
63	17	17	68	34	34	136	136	4	4	0	34	20	7	7	14	14	14	34	4	7	30	17	17	
64	10	10	40	20	20	80	80	2	2	0	20	20	2	2	4	4	4	20	2	2	30	10	10	
...
...
...
...
68	1 829	1 829	7 316	3 658	3 658	14 632	14 632	386	386	1460	3658	1360	730	730	1460	1460	1460	3 658	1 829	730	2 040	1 829	1 829	

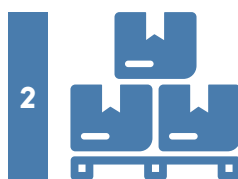
PHU, peripheral health unit; AS-AQ, artesunate + amodiaquine

Annex 6

STEP-BY-STEP PROCEDURE FOR PREPOSITIONING SUPPLIES



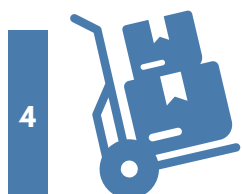
1 Identify and train the person who will be responsible for following up and managing stocks at each distribution point.



2 Calculate the quantity of medicines to be dispatched to each distribution point according to the estimated target population of the catchment area by age group.



3 Include a buffer stock. It may be advisable to keep part of the buffer stock (about half) in a central or district storage place to ensure capacity to react to unpredicted shortages.



4 Organize all other necessary logistic material into kits to simplify distribution. The amounts per kit should be calculated according to the numbers of teams and supervisors.



5 Calculate the volume and weight of the supplies in order to organize adequate transport.



6 Use tracking tools, such as waybills, for transport of supplies, with details of quantities and batch numbers to ensure traceability.



7 Deliver the material.

Upon reception of the order, the person responsible in each peripheral health facility should verify that the delivered goods correspond to those listed on the waybill before signing the receipt form.

CC: Icons created by Gan Khoon Lay, BomSymbols, Symbolon, Jose Morbán, Sribala, David, BomSymbols Maxim David, ProSymbols for the Noun Project

Annex 7

EXAMPLE OF RADIO SPOT ON MDA FOR MALARIA (USED IN SIERRA LEONE IN 2014–2015)

V1. Good morning, friend!!

V2. Good morning. How are you?

V1. Fine. Yesterday, I received the blister for the malaria treatment. Did you?

V2. Yes. All my family and I took the first dose yesterday in the afternoon. And you?

V1. No, we didn't take it.

V2. Why didn't you take it?

V1. Because nobody in the family has fever.

V2. In our family nobody had fever, but we took it to prevent malaria fever because we don't want to get sick.

V1. But before we never took it when we were not sick. Why should we do it now?

V2. Because now there is an EVD outbreak ongoing, so if you have fever you can become a suspect of EVD. A lot of EVD symptoms can be mistaken with malaria symptoms. (*) In any case, you and your family will be protected against malaria for 1 month and it is for free.

V1: Ok, you are right. I'm going home now to start the treatment with my family.

V2: Do you remember how to take it?

V1: Yes. The community health worker explained to me that we have to take it during three consecutive days to finish the treatment properly.

V2: Do you have any other doubt?

V1: No, we are going to take the tablets according to the age category like the CHW told me. But if I have any doubt I will ask the CHW.

V2: Good!!!! Have a nice day

V1: You too and thank you. Now we will be malaria free!!!!

*This section should be adapted to each MDA situation

Annex 8

EXAMPLES OF DISCUSSION POINTS ON MDA FOR USE AT COMMUNITY MEETINGS

(ADAPTED FROM THOSE USED IN SIERRA LEONE IN 2014–2015)

1. What is MDA?
2. Goal of the campaign
3. The medication, how to take it and exclusion criteria
The medication: How to take it
Exclusion criteria (people who must NOT take it)
Stick to the medicine and dosage for the age group. Wrong doses can cause:
 - Incomplete treatment = incomplete protection
 - Overdose = increase in possible side-effects
4. Possible side-effects and what to do
5. Explanation of the process
6. Roles of community leaders
 - ensure community awareness and acceptance of the campaign
 - sensitize importance of adherence (taking full treatment)
 - ensure awareness of correct dosage
7. Role of distributors and CHWs
 - sensitize community before and during MDA
 - distribute antimalarial tablets to target beneficiaries
 - tally all medicines distributed with the data collection tools
8. Team members: Two CHWs per team will be assigned by area and community.



Annex 9

HOUSEHOLD VISIT FOR MDA, STEP BY STEP

MASS DRUG ADMINISTRATION, VISIT STEP BY STEP



1
Greet the people politely in local language and introduce yourselves. Ask for the head of the household and verify whether all members of the household are present. Explain the objectives and provide information about the MDA using visual aids.



2
Obtain oral consent to participate.



3
Check eligibility criteria - Exclusion criteria:
» First trimester of pregnancy
» Infants under 6 months old
» Known allergy to any of the medication
» Critically ill patients
» Contraindications to the medicines
Explain to excluded people why they don't receive the treatment.



4
For women of reproductive age (15–49 years old):
» If visibility pregnant (assume second or third trimester): she may receive the medicine
» If pregnancy not apparent: first trimester pregnancy should be excluded either based on personal history or on pregnancy test.



5
Distribution of an appropriate blister according to age category. Administer the first dose under DOT. For small children, crush the tablet and dissolve it with water. Repeat dose if vomiting occurs within 30 minutes of administration.



6
Educate the participants on how to take the remaining doses for day 2 and day 3 using a visual aid to support the explanations and/or printed leaflets. Provide clear messages on the need to ensure adherence to full treatment course. Provide information concerning possible side effects and what to do in case they occur.



7
Ask the members of the household if they have any specific questions and clarify any doubts they may have.



8
Mark the tally sheet after the person has taken the first dose and/or fill in the registration book.



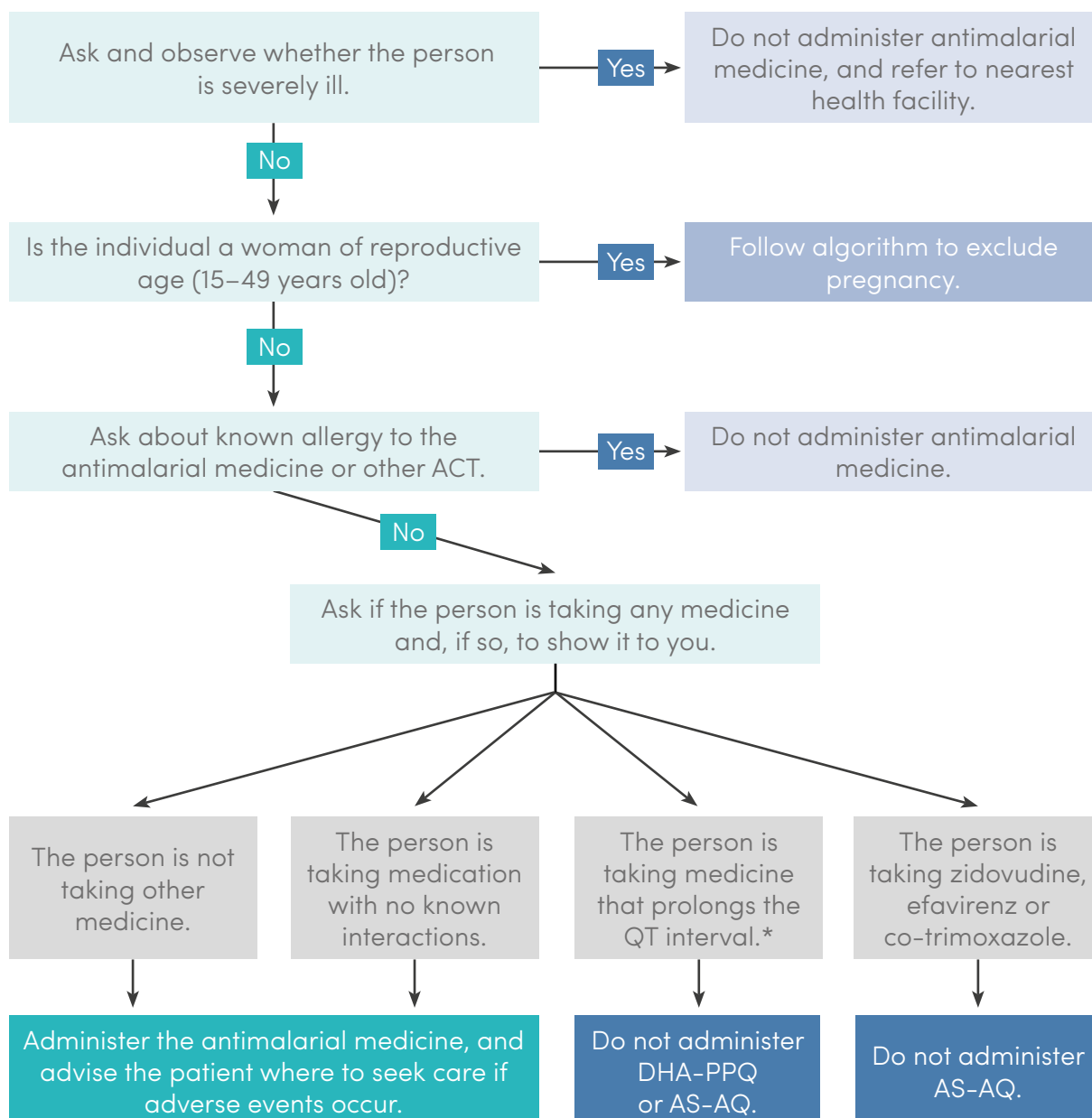
9
Thank the household members and move to the next household. Where applicable, upon departure, mark the house with chalk as either "complete", "incomplete" and if no one is home at the time of the visit, do not mark it.



10
Revisit the house at a later time in the day or the following day in the case that the distribution was incomplete or no one was home.

Annex 10

ALGORITHM TO ASSIST COMMUNITY HEALTH WORKERS IN APPLYING EXCLUSION CRITERIA



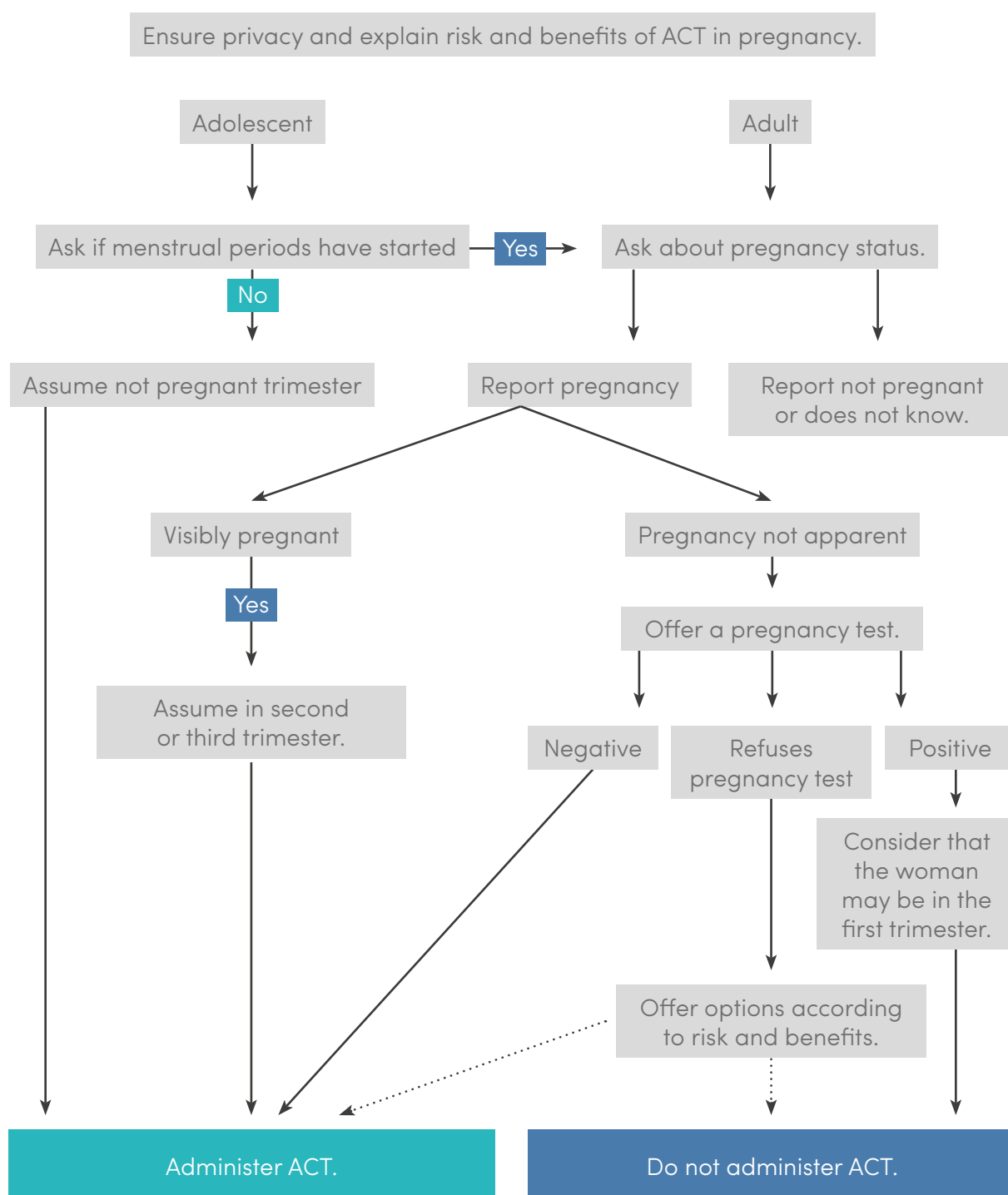
* A list of medicines that prolong the QT interval that are available and are the most frequently used in the country should be given to the CHW.
DHA-PPQ, dihydroartemisinin-piperazine; AS-AQ, artesunate-amodiaquine



Annex 11

ALGORITHM FOR DETERMINING THE PREGNANCY STATUS OF WOMEN OF REPRODUCTIVE AGE (15–49 YEARS)

















(BASED ON AND ADAPTED FROM ALGORITHMS USED IN MALARIA MDA IN MOZAMBIQUE BY THE CENTRO DE INVESTIGAÇÃO EM SAÚDE DE MANHIÇA)



Annex 12

EXAMPLE OF LAMINATED LEAFLET USED BY COMMUNITY HEALTH WORKERS IN SIERRA LEONE IN 2014-2015 TO EXPLAIN TREATMENT DOSAGE

- Take the tablets **ONLY** according to age.
- Take tablets **each day for 3 consecutive days** (at the same time).

	DAY 1	DAY 2	DAY 3
 <p>6-11 months</p>	 <p>1 crushed baby tablet</p>	 <p>1 crushed baby tablet</p>	 <p>1 crushed baby tablet</p>
 <p>1-5 years</p>	 <p>1 young child tablet</p>	 <p>1 young child tablet</p>	 <p>1 young child tablet</p>
 <p>6-13 years</p>	 <p>1 child tablet</p>	 <p>1 child tablet</p>	 <p>1 child tablet</p>
 <p>Adult</p>	 <p>2 adult tablets</p>	 <p>2 adult tablets</p>	 <p>2 adult tablets</p>

- For children, crush the tablet in a clean eating spoon and mix with water.
- This treatment may cause temporary side effects (vomiting, headache, dizziness, skin itch) which may last for 1 or 2 hours.
- This treatment protects against malaria for ONE month



Annex 13

EXAMPLE OF TALLY SHEET (ADAPTED FROM THAT USED IN SIERRA LEONE IN 2014–2015)

DAILY TALLY SHEET – ANTIMALARIA MDA

Team Number Day of campaign Zone/Area: Village/Neighbourhood:
 Date District: Health facility catchment area:

Total Households visited		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	Total:		
RESIDENCY STATUS		RESIDENT		VISITOR	
00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 Total:		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 Total:		00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 Total:	
Total distributed	Treatments distributed	6-11 MONTHS	1-5 YEARS	6-13 YEARS	14 YEARS AND ABOVE
	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 Total:	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 Total:	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 Total:	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 Total:	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 Total:
Total excluded	Cases excluded due to refusal to participate	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 Total:	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 Total:	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 Total:	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 Total:
	Cases excluded due to pregnancy (1st trimester)				
	Cases excluded due to other exclusion criteria	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 Total:	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 Total:	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 Total:	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 Total:

Daily monitoring of antimalarial consumption

BLISTER PACK	NUMBER OF BLISTERS RECEIVED	NUMBER OF BLISTERS REMAINING AT THE END OF THE DAY	NUMBER OF BLISTERS USED
Blisters 2-11 months (4.5 kg- 9 kg)	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 Total:	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 Total:	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 Total:
Blisters 1-5 years (9-18 kg)	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 Total:	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 Total:	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 Total:
Blisters 6-13 (18-35 kg)	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 Total:	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 Total:	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 Total:
Blisters ≥ 14 years (> 35 kg)	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 Total:	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 Total:	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000 Total:

Name of Team Leader: Name of Supervisor:

Note: age groups should be adapted to blister presentation of antimalarial medicine used

Annex 14

EXAMPLE OF A HOUSEHOLD REGISTRATION FORM

(ADAPTED FROM THE ZAMBIA MDA PROGRAMME DELIVERY HANDBOOK)

HOUSEHOLD REGISTRATION FORM

District Health facility catchment area Name of CHW

Zone Village Name

Household Number/ID	Head of household	Date	Name of participant	Age (years)	Sex (M/F)	Relation to head of household	Occupation (C: child, S: student, H: housewife, F: farmer, U: unemployed, O: other)	Residency status (P: permanent resident, V: visitor)	Resent at the time of visit (Y/N)	Received treatment (Y/N)	If treatment not received, state reason (R, refusal E: exclusion criteria)	State reason for refusal to participate D2	DOT			Comments
													D1	D2	D3	
1																
2																
3																
4																
5																
6																
7																
8																
9																
10																
11																
12																
13																
14																
15																



Annex 16

EXAMPLE OF MDA CARD

MALARIA MDA CARD FOR PARTICIPANT

District Health Center

Name Age

Address Weight

		DATE	TREATMENT PROVIDED	NUMBER OF TABLETS	DOT (Y/N)	OBSERVATIONS
ROUND 1	D1					
	D2					
	D3					
ROUND 2	D1					
	D2					
	D3					
ROUND 3	D1					
	D2					
	D3					



Annex 19

EXAMPLE OF STANDARD TEMPLATE FOR REPORTING A SUSPECTED ADVERSE DRUG REACTION



PATIENT DETAILS

Name Date of report:

Age Sex Weight (kg)

Address:

Pregnant: Yes No

If yes, trimester of pregnancy

Hospital or treatment centre

Relevant medical history

SUSPECTED DRUG OR PRODUCT

Brand name Strength Generic name

Name of manufacturer Daily dose

Date of manufacture Expiry date Batch number

Starting date of medication Route of administration

Drug discontinued because of event: Yes No Date

DRUGS OR PRODUCTS TAKEN CONCOMITANTLY (INCLUDING HERBAL MEDICATION)

Specify brand and generic name, dosage, route, day started, day stopped

.....
.....

ADVERSE REACTION

Details of the reaction experienced by the patient:

.....
.....
.....

Date and time the reaction started Date and time the reaction ended

Did patient require hospital admission? Yes No Duration of hospitalization

Reason for reporting

- Requires or prolongs hospitalization Life threatening Death
 Permanently disabling or incapacitating Congenital anomaly Overdose
 Other (please specify).....

CONDITION OR OUTCOME AT TIME OF LATEST OBSERVATION

- Full recovery
 Ongoing illness
 Persistent, significant disability, incapacity
 Other (please specify).....

DETAILS OF HEALTH CARE PROFESSIONAL OR REPORTER

Name Function.
Address Telephone number

Signature Institution

GUIDELINES FOR FILLING IN THE FORM

An adverse event is “serious” if it

- is life threatening
- results in hospitalization
- prolongs hospitalization
- causes malignancy
- is an overdose resulting in clinically relevant signs and symptoms
- results in permanent disability
- is fatal
- causes a birth defect
- causes relevant organ toxicity

An adverse drug may be a manifestation of:

- complications of an underlying disease
- coincidental accident
- concomitant medication
- intercurrent disease
- drug-associated effect



Annex 20

EXAMPLE OF QUESTIONNAIRE FOR POST-MDA SURVEY

Village Cluster no.

Household no. Survey date

Interviewer's name Supervisors' names

The following questions should be asked of each person over 6 months of age
(parent or guardian of children).

A. SOCIODEMOGRAPHICS

1) Age (years)

2) Sex: Male Female

3) Status of residence in the household: Permanent Temporary visitor

4) Marital status:

Single

Married

Widower or widow

Divorced or separated

Uncertain or no response

5) Level of education completed:

None

Primary level

Secondary level

Tertiary level (college or university degree)

Uncertain or no response

6) Occupation:

Student

Farmer

Herdsman

Merchant or trader

- Constructor
- Driver
- Professional or civil servant
- Labourer (daily, seasonal or long-term)
- Retired or too old to work
- None or unemployed
- Uncertain or no response
- Other. Specify:.....

B. INFORMATION ON MDA CAMPAIGN

1) Were you informed about the malaria MDA campaign?

- Yes No Uncertain or no response

2) Did you receive the malaria medication during the campaign?

- Yes No Uncertain or no response

If yes, go to question 4.

3) Why didn't you receive the medicines?

- I was travelling or I was not in town
- I was too busy to wait for the distributors or to go to the distribution site
- I do not trust the organizers of the campaign or the ministry of health
- Malaria is not a problem for me
- I never take any medicine
- I only take traditional medicine
- I did not know what the medicine was for
- I was pregnant
- I was taking other medicine at the time
- I was too sick
- I am allergic to the medicine
- Other. Specify.....
- Uncertain or no response

Questionnaire ends here.

4) Did the person who gave you the medicine watch you take the first dose?

- Yes No Uncertain or no response



5) Did the person who gave you the medicine explain to you how to take the next doses?

Yes No Uncertain or no response

If no, go to question 7.

6) Tell us how she or he explained how to take the medicine.

Correctly Incorrectly Uncertain or no response

The interviewer should mark "correctly" or "incorrectly" according to the interviewee's explanation.

7) How many doses of the medicine given by the distributor did you take?

- None
- 1 dose
- 2 doses
- 3 doses
- Uncertain or no answer

8) Can you show us evidence that you completed the treatment (empty blister or pill count)?

Yes No

9) Did you take the complete treatment as recommended?

Yes No Uncertain or no response

If yes, go to question 11.

10) Why didn't you take the treatment as recommended by the distributor?

- I forgot to take the medicine.
- I did not want to take it. Reason:
 - I was too sick
 - I saved the tablets for when I get sick
 - I gave the treatment to or shared the treatment with someone else
 - I was afraid of side-effects of the medicine
 - I was told by a family member or friend not to take it
 - I was told by a health professional not to take it
 - Other people became sick after taking the medicine
 - The medicine tastes disgusting
 - Other, specify
- Uncertain or no answer

11) Did you experience any side-effects after taking the medicine?

Yes No Uncertain or no response

If no, end of questionnaire.

12) Which side-effects did you have? (More than one answer possible) :

- | | |
|---|---|
| <input type="checkbox"/> Skin reaction | <input type="checkbox"/> Dizziness |
| <input type="checkbox"/> Abdominal pain | <input type="checkbox"/> Difficulty in sleeping |
| <input type="checkbox"/> Nausea and/or vomiting | <input type="checkbox"/> Drowsiness |
| <input type="checkbox"/> Diarrhoea | <input type="checkbox"/> Heart palpitations |
| <input type="checkbox"/> Loss of appetite | <input type="checkbox"/> Weakness |
| <input type="checkbox"/> Headache | <input type="checkbox"/> Other, specify..... |

13) How long after taking the tablets did you experience the side-effect?

- Less than 30 min
 Between 30 min and 1 h
 Between 1 h and 24 h
 Other. Specify

14) How did you manage the side-effect?

- I did nothing
 I took some medicine
 I visited a health professional or health facility
 Uncertain or no answer

15) Did you know of any emergency centre or hotline to call in case of side-effects?

- Yes No Uncertain or no response

If no, end of questionnaire.

16) Did you call the emergency centre or hotline for help?

- Yes No Uncertain or no answer



Annex 21

EXAMPLE OF PHARMACOVIGILANCE PREPAREDNESS CHECKLIST

(USED IN SIERRA LEONE IN 2014–2015)

Instructions

This is a working document. Start using it now by ticking (✓) those items that have been accomplished.

District:

Chiefdom

Facility

SUBJECT		COMPLETED	COMMENTS
Staff			
1. Is at least one person aware of pharmacovigilance monitoring during the artesunate–amodiaquine campaign?			
2. Have all staff been apprised of the basics of pharmacovigilance monitoring?			
3. Have all staff been trained in recognizing ADRs?			
4. Do all staff know the correct dose of artesunate–amodiaquine?			
5. Is a plan in place to cover hard-to-reach areas?			
5. Is there a map of the catchment area?			
5. Are there adequate quantities of the following (Assess quantities supplied against target population)	artesunate–amodiaquine		
	oral rehydration salts		
	paracetamol		
	chlorphenamine		
Advocacy and social mobilization			
1. Has there been a health talk in the community about compliance and adherence to artesunate–amodiaquine?			
2. Is information available at the public health unit about ADR monitoring?			

Name of person completing the checklist

Signature Date

Annex 22

EXAMPLE OF AN MDA PHARMACOVIGILANCE TRAINING MODULE

CURRICULUM FOR DRUG DISPENSERS

The curriculum is divided into four modules, based on the chronology and structure of the WHO–ISOP curriculum (1). The content should be adapted to the pharmacovigilance requirements in the country and opportunities taken to integrate it with other training sessions for drug dispensers.

Introduction

The curriculum is based on several packages of topics and concepts of PV teaching used by WHO and WHO collaborating centres (2). It was designed for programmes of seasonal malaria chemoprevention and adapted for use in malaria MDA.

Purpose of the course

The aim of the course is to enable health workers and drug dispensers to detect, report and follow-up on suspected adverse drug reactions during malaria MDA.

Target group

The course is designed for drug dispensers involved in MDA, who may have very limited medical knowledge but are present in the community at the time of the operation. They interact directly with all household members when administering the first dose, dispense and counsel carers on administering the remaining doses and provide advice on possible adverse drug reactions and where to report them. They should be able to refer people with serious adverse events and report them.

Course duration

The material is designed to be covered in 1 day. Sections can be reduced and prioritized if training time is limited.

Course content

Module one: What are adverse drug reactions and why should we monitor them?

- Importance of adverse drug reactions in the context of MDA

Module two: Adverse drug reactions and medication errors

- Serious adverse drug reactions
- Adverse events associated with medicines and concomitant medication
- Administration of medicines in MDA, medication errors and their consequences, particularly over-dosing



Module three: Reporting suspected adverse reactions

- Completion and use of reports and referral notes

Module four: Communication

- Effective communication with patients and health professionals
- Managing rumours at community level

References

1. Beckmann J, Hagemann U, Bahri P, Bate A, Boyd IW, Dal Pan GJ et al. Teaching pharmacovigilance: the WHO-ISoP core elements of a comprehensive modular curriculum. *Drug Saf.* 2014;37:743–59.
2. ISoP – PV curriculum – search. London: International Society of Pharmacovigilance; 2017 (<http://isoponline.org/pv-links/>, accessed 17 August 2017).

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ISBN 978-92-4-151310-4

