
Pre-referral treatment with rectal artesunate of children with suspected severe malaria: a field guide



World Health
Organization

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Acronyms

ACT	artemisinin-based combination therapy
CHW	community health worker
iCCM	integrated community case management
IMCI	integrated management of childhood illnesses
PHC	primary health care
RAS	rectal artesunate
SBCC	social and behavioural change communication

1. Introduction

Malaria is one of the leading causes of illness, death and lost economic productivity globally. While there has been a widespread increase in use of critical intervention strategies, malaria still causes over 600 000 deaths each year, mostly among children under 5 years of age and pregnant women.

Prompt, effective antimalarial treatment and supportive care can substantially reduce the rate of mortality from severe malaria (1).¹ Many children, however, do not have access to a qualified health care provider and do not receive the necessary care in a timely fashion. Without rapid detection of danger signs and access to effective treatment, including pre-referral treatment that can be administered in the community level, many children with severe malaria die.

Since 2005, WHO has recommended immediate administration of a standard dose of an effective antimalarial medicine as pre-referral treatment of patients with severe malaria before referring them to a facility at which complete treatment can be administered. In 2015, rectal artesunate (RAS) suppositories for pre-referral treatment of severe malaria in children aged < 6 years was included as an option in the third edition of the guidelines for the treatment of malaria (2). RAS rapidly clears 90% or more of malaria parasites and can reduce the risk of death or permanent disability by up to 50% in children who cannot reach a facility in fewer than 6 hours (3). Quality-assured RAS became available in 2018, and several countries in Africa have included its use in their national treatment guidelines.

An operational study was conducted in the Democratic Republic of the Congo, Nigeria and Uganda between 2017 and 2020 to understand and identify the minimal requirements for use of RAS to achieve the desired effect. The results of this study and those from other countries in which it had been used provide the evidence in this field guide for effective introduction of RAS in countries.

¹ The WHO guidelines for malaria are also accessible online at <https://app.magicapp.org/#/guideline/7661>

2. WHO recommendation for use of rectal artesunate (RAS)

WHO recommends that: “where intramuscular injection of artesunate is not available, treat children < 6 years with a single rectal dose (10 mg/kg body weight) of artesunate, and refer immediately to an appropriate facility for further care. Rectal artesunate should not be used in older children and adults”.

RAS is a pre-referral intervention for children < 6 years with features of severe febrile illness (severe malaria) who do not have immediate access to a health facility that can provide full treatment while the patient is being moved to a referral facility for further care and treatment with injectable artesunate followed by a full course (3 days) of an ACT. WHO recommends that children be given a single rectal dose of artesunate and referred immediately to an appropriate facility. The intervention reduces the risk of death or permanent disability by up to 50%.

This field guide is aimed at supporting the effective deployment of RAS as pre-referral treatment of suspected severe malaria in line with the WHO malaria guidelines.

The main considerations are:

Defining the population for RAS: RAS should be used for pre-referral treatment of children < 6 years with suspected severe malaria only when injectable artesunate is not available. In children > 6 years, RAS is associated with increased mortality. RAS is not appropriate and is not recommended for uncomplicated malaria, which should be treated with oral artemisinin-based combination therapy (ACT).

RAS is pre-referral treatment: RAS should be used as part of a continuum of care and should not be considered full treatment for severe malaria. All patients who receive RAS should be assisted in reaching a referral health facility quickly for complete, appropriate treatment with injectable artesunate and ACT and other supportive care for severe malaria. A functional, effective referral system is essential to ensure the impact of RAS on mortality.

Risk of monotherapy: RAS and injectable artesunate should not be used as monotherapy but should always be followed with a complete course of ACT, ideally provided in primary health care (PHC).

Resistance must be monitored: Countries should ensure continued monitoring of the therapeutic efficacy and drug resistance of antimalarial medicines, as recommended by WHO.

3. Inclusion of RAS in national malaria treatment guidelines

The decision at national level to adopt and use RAS as part of national treatment policy should involve all relevant stakeholders, including technical, implementing, and financial partners, led by the national malaria control programme.

Countries with a high burden of severe malaria in children, especially in areas far from high-level health facilities with inpatient capacity to provide appropriate management of severe malaria, should decide whether and how to include RAS in their national malaria treatment guidelines. Once a decision is made to include RAS in the guidelines, a conducive national policy and regulatory authorizations should be established to ensure sustained coverage in geographical areas where RAS is needed.

3.1 Adoption of RAS in the national treatment policy

An appropriate taskforce or technical working group(s) established by the national malaria control programme should lead discussions to adopt RAS in the national case management strategy according to WHO published guidance for development of national malaria treatment guidelines (1) and the national malaria strategic plan (4). The child health and community health departments should be represented in the working group, and all national stakeholders should be adequately engaged.

Before deciding to introduce RAS into the national treatment policy, a situation analysis should be conducted to establish the burden of severe malaria and gaps in the continuum of care between communities and referral health facilities. The conclusion should determine where and how RAS should be deployed to achieve the objectives of the national programme. The result should also provide a baseline against which the outcome of RAS can be compared over time.

The situation analysis should be conducted at all levels to determine:

- the distribution of severe malaria in various parts of the country to indicate where RAS should be a priority, especially remote peripheral and hard-to-reach communities and those with limited access to quality health care;
- the status of implementation of integrated community case management (iCCM) and integrated management of childhood illnesses (IMCI) to assess where RAS can be introduced;
- where feasible, the status of the referral system, from community to referral facilities, and the rate of referrals in remote, peripheral and hard-to-reach communities, in addition to those with limited access to good-quality health care;
- the availability of supplies for diagnosis and treatment of severe malaria in health facilities by community health workers (CHWs), especially at referral level;
- the availability of functional supervision and support systems for CHWs in PHC facilities where RAS could be deployed;

- functional procurement and supply chain management at community level in areas in which RAS could be used;
- capability in referral facilities for management of severe malaria, including blood transfusion and laboratory services;
- reporting system to capture data on and use of RAS, completion of referral and follow-on treatment of severe malaria in a hospital;
- strengths and weaknesses of the pharmacovigilance system;
- strategies for advocacy for community and social mobilization; and
- potential sources of additional funding for effective deployment of RAS.

3.2 Minimal essential requirements for RAS

To be effective, RAS requires minimal health system elements (Table 1). Countries should not base a decision to use on these requirements but rather work to strengthen the health system for optimal RAS implementation.

Table 1. Essential minimum considerations for RAS deployment

Consideration	Minimal requirements
Treatment seeking	
<ul style="list-style-type: none"> • Role of the private sector (clinics, chemists, pharmacies) 	<ul style="list-style-type: none"> • Private sector recognized as an important stakeholder and equipped accordingly to provide adequate care and/or advice • Consider RAS pre-referral treatment by private providers. • Manage health care system comprehensively, with all relevant actors, including the private sector.
<ul style="list-style-type: none"> • CHWs are often not the first source of care for cases of severe malaria. 	<ul style="list-style-type: none"> • Ensure consistent presence of CHWs in the community by adequate training and consistent supervision. • Ensure that CHWs are skilled, trusted and recognized as first points of care, particularly when health facilities are hard to reach. • Strengthen the supervision system, especially CHW case management skills. • Strengthen procurement and supply management to ensure that CHWs always have the full package of diagnostic and treatment commodities.

Consideration	Minimal requirements
Treatment in the community	
<ul style="list-style-type: none"> • Acceptance of RAS is good, and use is high when the product is available. • RAS is frequently underdosed in children ≥ 3 years. • Large differences between the number of providers and the number of patients treated 	<ul style="list-style-type: none"> • Ensure the availability of malaria case management or iCCM. • Ensure a functioning supply chain and sufficient stock per provider; supply to be balanced against shelf-life • Ensure availability of diagnostics and other drugs required for case management. • A functional, sustainable commodity tracking system and easy access to resupply • Regular mentoring and supervision, especially building and maintaining CHW clinical skills
<ul style="list-style-type: none"> • Injectable antimalarials are sometimes administered at PHC level. 	<ul style="list-style-type: none"> • System of training and retraining for those who administer RAS and follow-up with a full course of ACT
Human resources	
<ul style="list-style-type: none"> • High CHW turnover 	<ul style="list-style-type: none"> • Support for CHW retention (proper incentives for services provided) • Community engagement for CHW support • Regular retraining of CHWs • Supportive supervision, including proper linkage to PHC facilities to improve the quality of care
Referral	
<ul style="list-style-type: none"> • Referral from CHW to PHC rather than to a designated referral facility may delay or preclude full treatment. • Rate of referral from CHW to PHC often $< 60\%$ 	<ul style="list-style-type: none"> • Patients should be referred directly to a facility that can offer emergency care and adequate post-referral treatments (in the case of severe malaria usually secondary or tertiary facilities) • Support for impoverished communities, e.g. subsidised emergency transport system or social health insurance schemes to support increased completion of referral

Consideration

- Referral may be less likely for patients treated with RAS (especially if administered in PHC), possibly due to rapid clinical improvement after RAS.
- Patients who are not referred are less likely to receive ACT.

Minimal requirements

- System for referral to adequate facilities should be strengthened (with consideration of referral facility capacity and resources to alleviate financial barriers of referral)
- Strategies to create and sustain community awareness about completion of full treatment are necessary.
- Affordable referral support (e.g. subsidized transport)
- A “back-up plan” for children who do not complete referral to prevent deterioration, e.g. ensure follow-up and full course of ACT
- When referral is not immediately possible, health workers may consider repeating RAS administration while referral is pursued. Complete ACT should then be given as soon as the patient can swallow. Note: This should be an exception and not the norm.

Post-referral case management

- Many children do not receive injectable artesunate and an ACT after RAS.
- Children who do not receive the full treatment course for severe malaria are more likely to die or be ill on day 28.
- Most children die several days after attending a health facility (PHC or referral health facility).
- Ensure that a full course of ACT is dispensed in PHC and that at least the first dose was taken before discharge from PHC.
- Strengthening procurement and supply management
- Provide appropriate information to caregivers
- Monitoring and evaluation to ensure full ACT
- Ensure standard and appropriate case management (full treatment of severe malaria and comorbidities) at the facility.
- Follow-up visits by the primary health provider to the sick patient to track referral completion of possible defaulters, if indicated. This may also help to build trust in PHC workers.

Regulatory systems

- The package of commodities that CHWs can administer in the community varies considerably by country.
- Ensuring a consistent policy to allow CHWs to administer the full package of recommended interventions for iCCM (including RAS) will help to increase confidence in pre-referral treatment of severe malaria by CHWs.

Consideration	Minimal requirements
Routine health information systems	
<ul style="list-style-type: none"> Data reporting systems in countries are generally weak, especially in communities. 	<ul style="list-style-type: none"> Inclusion of community data in DHIS-2 will improve tracking, targeting of RAS supply and ensuring its appropriate use. Integrate RAS into other supply chain data elements to ensure a harmonized package of services.
Procurement and supply chain management	
<ul style="list-style-type: none"> Supply chain systems are generally weak. 	<ul style="list-style-type: none"> Quantification to support accurate determination of needs will ensure appropriate supply and distribution and to reduce expiry of drugs. Functioning logistics management information system Qualified, capacitated logisticians to track availability and consumption and rapidly redistribute to avoid stock-outs
Sustained financing	
<ul style="list-style-type: none"> iCCM programmes are sustained by various agencies, and none funds all components. Malaria is often a core contributor to funding for iCCM, Health systems strengthening generally receives limited domestic investment. 	<ul style="list-style-type: none"> Concerted planning by the ministry of health to ensure that all components of the continuum of care for childhood diseases are funded Investment should be increased progressively. The private sector should be engaged progressively in the provision of good-quality care.

3.3 Updating of national malaria treatment guideline to include RAS

When a country decides to include RAS for children under 6 years of age in its malaria case management strategy, the national malaria treatment guideline and supporting tools should be updated. The strategic documents that should be updated may include:

- the country's strategic or operational plans,
- the national malaria treatment guidelines,
- iCCM and IMCI guidelines and
- the national essential medicines list.

It should be made clear that, when intramuscular injection of artesunate is not available, children < 6 years of age should be given a single rectal dose (10 mg/kg body weight) of artesunate and referred immediately to an appropriate facility for further care and treatment with injectable artesunate, followed by a full 3-day course of ACT once the patient can tolerate oral medication. Do not use RAS for older children or adults.

3.4 Updating of national ICCM and IMCI guidelines to include RAS

Once the national malaria treatment guidelines include RAS, national programmes such as the iCCM and IMCI should include use of RAS for pre-referral treatment of suspected severe malaria in children < 6 years of age in the context of the national community delivery strategy and the WHO recommendations on RAS.

Elements of the community strategy that could be considered in implementation of RAS include delivery of RAS through the country's community health system (iCCM and IMCI) and inclusion of a rapid diagnostic test for testing for fever as part of iCCM strategy. This is not an essential requirement for administration of RAS by CHWs. CHWs should be enabled and equipped to dispense RAS.

3.5 National registration of RAS and inclusion on the national essential medicine list

RAS registration and subsequent inclusion on the national essential medicine lists is critical to ensure procurement by funders to ensure drug supplies for the public sector. The steps and processes for including RAS on the national list of essential medicine should be activated. Some countries may have lengthy processes for registration, and the process should be initiated as early as possible. Dispensing of RAS should be ensured by CHWs.

4. Planning use of RAS

Once the RAS strategy has been integrated into the national malaria treatment guidelines and relevant community programmes, a detailed macro and micro implementation plan should be prepared. RAS should be included in the strategy for iCCM.

Plan implementation, and estimate the necessary human, logistics and financial resources. Note that RAS is an integral part of case management of malaria and should be part of the plan for overall case management. Avoid setting up parallel, independent pathways, including supply chains, capacity and supervision for RAS. Build and strengthen existing case management structures.

The following activities should be addressed in the implementation plan:

- coordination of national, regional, district and community implementation;
- RAS delivery strategy;
- commodity and supply chain management;
- training and supervision of personnel;
- advocacy and community mobilization;
- monitoring and evaluation; and
- costing and budgeting.

4.1 National coordination of RAS implementation

The ministry of health through the national malaria programme should provide overall leadership and oversight, including coordination, in collaboration with the department of community and child health or a similar ministry of health department and non-state actors responsible for health-care delivery in the community. The coordination group should include all partners that provide services for malaria case management. The programme should consider using existing oversight committees or bodies (iCCM, IMCI, child health committee or task force) to oversee and coordinate planning, implementation and monitoring of RAS for malaria case management. A coordination committee, task force or working group should develop a clear work plan for full implementation of RAS.

4.2 Delivery of RAS

The distance of and the time for accessing a referral facility are important factors in adopting and planning RAS implementation. RAS has been shown to reduce mortality due to malaria in situations in which the estimated time to referral is > 6 h. RAS should be used in community case management when access to management of severe disease is limited. Functional referral systems should be available to ensure that patients have access to complete, timely treatment after administration of RAS.

Operational studies have shown that RAS can be delivered by CHWs and peripheral health workers in remote areas to reduce parasite density before the patient is referred to an appropriate level of care for full treatment. RAS delivery should

therefore be guided by the country's community health strategy, through one of the following channels:

- the community health system as part of the iCCM algorithm for children with severe febrile illness;
- peripheral health facility systems as part of the IMCI algorithm for children with severe febrile illness; or
- the private sector system, where applicable and appropriately supervised, with referral services integrated into the public sector. In many countries, the private sector is engaged mainly in social and behavioural change communication (SBCC) for recognition of danger signs and to ensure prompt referral.

Countries may have other service providers or mechanisms for RAS administration, such as mobile drug vendors, traditional healers or religious leaders, who provide care for children with severe febrile conditions. Although they may not currently administer RAS, their role in SBCC and referral should be recognized.

Irrespective of the mechanism of RAS deployment, the following conditions should be considered:

- *Availability of RAS and supply management.* RAS should be procured and distributed to CHWs and peripheral health facility workers in remote areas in quantities commensurate to the incidence of severe malaria in children < 6 years. The temperature for storage should not exceed 30 °C, and capacity should be available for storage for < 6 months.
- *Care-seeking.* Tailored SBCC messaging should be used to encourage caregivers to seek treatment for severe febrile illnesses by CHWs, the effect of early treatment with RAS for children < 6 years, and the importance of immediate referral to hospital for complete treatment and cure. This will improve care-seeking behaviour, acceptance of RAS and referral.
- *CHW or peripheral health facility.* All personnel in the continuum of care should be trained and supported in administering RAS as part of malaria case management. CHWs and peripheral health facility workers should be trained to identify danger signs and when and where to refer patients. They should be supervised and supported in their work through job aids and training modules for identifying severe febrile illness, administration of RAS and prompt referral.
- *Referral.* When referral and high-quality care are assured, administration of RAS can reduce mortality in children < 6 years by about 25% (2). The system for full referral from communities in remote areas to appropriate higher-level facility should be strengthened. The national and district programmes should strengthen referral from remote areas, with consideration of distance and cost of transport to referral facilities to ensure that they are not barriers to completion of referral. Experience from countries that have used RAS include community initiatives to facilitate patient transfer, provision of incentives, provision of ambulances and other means of transport by local governments, provision of referral maps to CHWs, and partnership with local transporters. Countries could consider such interventions and other feasible interventions according to their context.

- *Referral health-care facilities.* These facilities should have an effective system for patient triage and be fully equipped to care for patients with severe malaria who either go directly to the facility or are referred from communities and peripheral health facilities. Efficient referral has a strong impact on patient outcomes and caregiver confidence in the referral system. A referral note may be useful for tracking referral and reporting back to the referring health worker. (See Annex 1 for an example of a patient referral note.)

4.3 Commodity and supply chain management

Good quantification, procurement, distribution, storage and appropriate re-supply determine successful implementation of RAS. The national malaria control programme in collaboration with the central medical store should develop a supply chain management plan to ensure an uninterrupted supply to minimize expiry and stock-outs.

Quantification of RAS: The quantity of drug requires approximation of the expected incidence of severe malaria in children < 6 years in the areas targeted for deployment. Morbidity or consumption maybe used to estimate the RAS requirement for targeted areas. Examples of the assumptions and data sources for estimating consumption are shown in Table 2.

Table 2. Quantification of RAS

Assumption	Source of data
Number of CHWs in the targeted area(s)	District data from iCCM
Percentage of CHWs expected to see one suspected severe malaria case per month	iCCM data
RAS requirement per CHW per month	
Number of health facilities that require RAS in the targeted area(s)	District data
Percentage of health facilities expected to see one case of suspected severe malaria per month	District data
RAS requirement for peripheral health facilities per month	
Basic monthly supply of RAS required for CHWs and health facilities that deliver RAS	
Monthly requirement for CHWs and health facilities including a 10% buffer stock (wastage, lead time, unexpected increase) (x 1.10)	

Procurement and distribution plans: The plan for procurement of RAS should be synchronized with procurement of other malaria case management commodities. The plan should detail:

- the total quantity of RAS 100 mg to be procured;
- the total quantities of associated commodities, such as gloves, to be procured;
- when orders will be placed and anticipated delivery dates; and
- the total cost of insurance and freight.

Storage of RAS: Artesunate suppositories tend to degrade and are generally less stable at temperatures > 30 °C. Procurers and distributors should therefore take care to avoid temperatures > 30 °C during storage and transport of the product.

As temperatures tend to be higher in remote areas where malaria transmission is higher (and the need for RAS greater) and storage at < 30 °C may be difficult, the product should be distributed to CHWs in limited amounts for short-term storage, generally not > 6 months within the shelf life the product.

To keep temperatures low, RAS can be kept in a watertight container in a bucket of water in a shaded spot. Concrete buildings are not suitable, as they radiate heat late in the evening. In peripheral health facilities, RAS could be kept in a refrigerator, if available.

RAS disposal: It is recommended that RAS that has not been used for 6 months be collected and disposed of according to the local drug disposal guidelines for expired medicines. This will reduce the risk that CHWs use RAS that has degraded.

4.4 Training

Capacity-building is essential at all levels of the health system for successful introduction of RAS into malaria case management. The technical committee of the national malaria control programme that oversees RAS should develop a plan in which regional, district and community health workers are trained as part of the malaria case management training strategy. Training materials can be updated from community case management manuals and/or iCCM and IMCI. The training materials should be in accordance with updated national treatment guidelines. (See Annex 1 for an example of a training curriculum for community and facility health workers.)

Health-care providers at all levels must all be trained in administering RAS and generating and using data, including on referral, completion of referral and treatment. The following should be considered when developing a plan for training and supervision.

- Training should be conducted in a cascade manner, with national training of trainers for “master trainers”, followed by training of trainers at regional and/or district level and training of health providers in communities, health posts and referral hospitals.
- In remote, hard-to-reach, underserved communities, health care is often delivered by various cadres of CHW. All should be targeted for appropriate training according to the national training framework. The curriculum should include identification of children with severe febrile illness, administration of RAS, proper referral practices and completion of reporting forms for data collection.
- Refresher training or training of new staff could be included in routine training within the national malaria control programme.

- Job aids with pictorial examples are useful for training personnel. (See Annexes 2 and 3 for an example of a RAS job aid.)
- The training material should be updated regularly at national level according to feedback from previous courses.
- The content of training courses should be adapted to the roles and responsibilities of the trainees. In addition to technical elements of RAS administration, the curriculum should empower providers to create demand, raise community awareness and sensitize them to ensure optimal uptake of RAS.
- Training at lower levels of care should be supervised by master trainers in order to maintain quality.
- Complete iCCM training should be the basis for successful RAS introduction at community level.
- RAS providers should regularly attend refresher training to ensure the quality of care and to reduce health worker attrition, as movement and hire of new health-care personnel are common.

4.5 Supportive supervision

Supportive supervision ensures that RAS implementation is in compliance with the ministry of health plan and procedures. The following should be considered in developing a supervision plan.

- Supervision of RAS implementation should be part of the general supervisory system and not a parallel system. (See Annex 1 for examples of supervisory training manuals and the iCCM supervision checklist.)
- A plan for supervision should be prepared for the national malaria control programme for all levels, through to community level. The plan should specify frequency, quality assurance during supervision and mitigation of gaps in support supervision.
- A plan for clinical mentorship should be developed to build the case management capacity of CHWs. The plan should specify frequency, skills assessment and steps to be taken to address any gaps identified during mentoring.
- A plan should be developed to promote strong links between CHW and PHC for supervision and mentorship.
- Intensive supportive supervision is necessary, especially during the early stages of RAS implementation, to identify and resolve problems. Supervision should include retraining as required for CHWs who experience difficulties.

4.6 Retention of the community workforce

Countries should take measures to retain CHWs for early detection of children with severe febrile illnesses, pre-referral treatment (including with RAS, as indicated) and prompt referral to higher-level facilities by offering incentives such as inclusion on the government payroll and provision of a monthly salary. If regular payment is not feasible, a subsidy should be provided to ensure the availability of CHWs for prompt, reliable pre-referral care (5). Another example is payment of transport fees to attend regular working sessions at the nearest PHC facility for a supply of RAS, data reporting and coordination.

4.7 Advocacy for community and social mobilization and behavioural change communication

Advocacy for SBCC is used to raise the awareness of community members and local leaders, technical and financial partners of the national malaria control programme and nongovernmental organizations involved in service delivery. These activities foster community health-seeking and uptake of RAS as part of the overall case management strategy. (See Annex 3 for an example of an RAS poster.)

Delivery of messages about RAS and severe malaria in children should reduce the risks of misunderstanding and negative perceptions about the strategy. Community members and district and national leaders should be involved in advocacy and social mobilization. A plan for SBCC should be prepared and implemented before and during RAS deployment. The plan should emphasize:

- the fact that CHWs have been trained and have the capacity to diagnose and treat uncomplicated malaria and to refer severe malaria cases to a referral facility;
- the benefits of RAS;
- the target group for RAS;
- the fact that children who receive RAS are not fully protected and may still become very ill with malaria if they are not referred to and receive complete treatment for severe malaria at referral level;
- the difference between pre-referral treatment and definitive treatment;
- the need for a continuum of care, from community to hospital level, for correct malaria case management;
- the importance of other malaria control strategies (such as treated bed nets); and
- rebuttal of negative rumours about RAS to limit their spread.

Material for advocacy and BCC should be prepared in the local language, field-tested, reviewed carefully with local experts and then translated into other local languages if appropriate. Communication should be provided through various resources, according to the country context, such as:

- mass media (radio, television and local newspapers);
- community organizations;
- community leaders;
- CHWs;
- community volunteers;
- health-care facilities; and
- market places and other public gathering places.

4.8 Budgeting and resource mobilization

The overall annual cost of implementation should be estimated and sources of funding identified, with funding gaps. Table 3 provides a template for an RAS implementation budget.

Table 3. Example of RAS implementation budgets

Activity	Unit cost	Total cost	Funder	Comments
Procurement and distribution				
Procurement				
Costs of distribution				
Training				
Trainers of trainers				
District training				
Training of CHWs				
Supervision				
Training of supervisors				
Supervision				
Advocacy and BCC				
Training				
BCC				
Total cost				

5. Roles and responsibilities in introduction of RAS

Various levels of the health system should play different and complementary roles to ensure optimal implementation of RAS as part of a comprehensive continuum of care for the management of severe malaria.

Countries should use existing arrangements for malaria case management services. Depending on the functionality of a tier system in the country, national, regional, district and community organizations should have designated roles to ensure optimal use of RAS in case management.

5.1 National malaria control and elimination programme

The responsibilities may include overall oversight, coordination and supervision of RAS implementation; and mobilization of resources for RAS uptake and use in the community system. The activities include:

- engagement of key stakeholders such as professional bodies and partners;
- preparation and review of the overall RAS implementation plan;
- integration of RAS into the national malaria treatment policy or guidelines;
- mobilization of funding for RAS procurement and roll-out;
- assisting preparation of regional and district implementation plans;
- coordination with the central medical store for procurement, distribution and regular monitoring of use and demand for malaria case management commodities, including RAS and malaria diagnostics;
- updating integrated case management training, supervision, recording and reporting;
- facilitation of training of trainers at national and/or regional level and supervision of training at district level;
- advocacy, information, education and communication at national level;
- liaison with partners, including those in research and academic institutions;
- compilation of national data and preparation of progress reports as necessary; and
- organization of regular meetings with stakeholders to review monitoring and evaluation results and use them to update implementation accordingly.

5.2 Regional health authorities

Their responsibilities may include oversight of RAS implementation in districts in the region and facilitation of district training and supervision.

Their activities include:

- managerial and financial supervision of malaria case management services, including RAS implementation in the region;
- ensuring adequate supplies of malaria case management commodities, including RAS;
- advocacy, information, education and communication for malaria control services, including severe febrile illness;
- facilitation and supervision of RAS implementation in districts in the region;
- facilitation of preparation of district micro plans and budgets; and
- collation and analysis of regional data for regular reports.

5.3 District health management team

Their responsibilities may include oversight of RAS implementation in community and health facilities in the district and facilitation of community and facility training and supportive supervision.

Their activities include:

- ensuring the acceptance of stakeholders;
- preparation of the district malaria case management implementation plan and budget, including RAS;
- promotion and dissemination of the RAS strategy as part of the continuum of care to the district health team and malaria implementation partners in the district;
- collation of data on consumption and forecasting and supply of malaria medicines (including RAS) and diagnostics for referral facilities, peripheral health centres and CHWs;
- establishment of an effective communication system for RAS implementation and to improve the continuum of care for severe malaria;
- preparation and training of CHWs for community advocacy and social mobilization and for case management;
- planning and organization of supervision of RAS deployment, referral and case management in referral facilities;
- monitoring progress and solving problems in RAS deployment, referral and case management at referral facilities; and
- ensuring that RAS is included in the reporting tools for the health management information system.

5.4 Referral facilities

Their responsibility is management of severe malaria cases referred to the facility.

The activities include:

- organization of meetings with personnel to explain the importance of prompt, effective case management of severe malaria at referral level as part of the RAS strategy;
- training health workers in referral health facilities in managing severe malaria as per national guidelines;
- reporting serious adverse events to the national pharmacovigilance centre;
- compiling monthly reports for submission to the district health office; and
- ensure availability of injection artesunate and ACTs.

5.5 Peripheral facilities

Their responsibilities include: management of malaria cases, including referral of severe conditions; training of CHWs; supervision of RAS implementation in communities; clinical mentoring of CHWs; advocacy and community mobilization; and detection and management of adverse events.

Their activities include:

- organization of meetings with all personnel in peripheral health facilities to explain the RAS strategy in case management;
- meeting communities to promote early health-care-seeking and to inform them on where to find help for childhood illness;
- in collaboration with community leaders, identification of community members who will participate in sensitization by making door-to-door visits and delivering messages at suitable gathering places such as markets, mosques and churches;
- collaboration with community leaders to identify CHWs;
- training of CHWs in the health facility catchment area in administering RAS and managing referrals;
- meeting the community to identify and discuss their concerns and reporting their concerns;
- preparation of a delivery and supervision plan for each village in the catchment area;
- dispatching of drug, consumables and monitoring forms to CHWs;
- supervision and support for CHWs as prescribed in the community delivery strategy; and
- compilation of routine reports from CHWs for submission to the district health office.

5.6 Communities

Their responsibilities include establishing committees for community governance of health and mobilization by community leaders and health workers. CHWs are responsible for administering RAS, referring children with severe febrile illness to appropriate facilities and referring patients with suspected adverse drug reactions to nearby health facilities.

The activities include:

- promoting the use of RAS in children with danger signs and referral to a designated referral facility;
- identification and referral to health facilities of children with reported adverse drug reactions;
- social mobilization in collaboration with selected community members and CHWs at peripheral health facilities;
- management of malaria supplies, including RAS, reporting and submitting stock status reports;
- completion of treatment registers and monthly reports; and
- conducting community awareness sessions for caregivers of children on referral of a child to the nearest point of care and the importance of adherence to a full treatment regimen, including injectable artesunate and full ACT treatment.

5.7 Private sector

The formal private health sector comprises private for-profit and faith-based not-for-profit facilities. The private sector can be involved through professional associations or by government authorities responsible for licensing. The private health sector should be included in plans for training, drug quantification and procurement, data collection and use, linked to the country's logistics management and health information systems.

Their responsibilities may include training private providers in administering RAS and referring children with severe malaria to referral facilities and conducting advocacy and community mobilization.

Their activities include:

- participation in training and re-training of private providers;
- assessing and administering RAS to children in the community and appropriate referral to health facilities;
- identifying and reporting adverse drug reactions to referral facilities or the district health office;
- stock management of malaria commodities and submission of stock status reports;
- completion of reporting forms and registers; and
- conducting community awareness for caregivers of children on referral of a child to the nearest point of care and the importance of adherence to a full treatment regimen, including injectable artesunate and full ACT treatment.

5.8 Other service providers

Children's caregivers may use informal sectors in the community, such as mobile drug sellers, traditional healers and religious leaders. Countries that are considering engagement with this sector should have a policy to allow them to administer RAS.

In the interim, this sector should be identified, mobilized and equipped with:

- information and materials for malaria control,
- information and skills for early recognition of danger signs in children, and
- information on referral of severe cases to health-care facilities.

6. Monitoring and evaluation

Monitoring is conducted routinely to oversee the essential elements of programme performance by record-keeping, surveillance and regular reporting. A good monitoring and evaluation system is based on both routine health information and periodic household and health facility surveys, which should be adapted to include questions relevant to RAS.

RAS should be integrated into the conceptual framework for monitoring and evaluation of malaria case management services.

6.1 Tools, data collection and data quality

To ensure good data collection and reporting, user-friendly tools should be made available for CHWs at all service points. The sources of data may include iCCM registers (Annex 1), health facility registers, hospital admission and discharge registers, and reporting forms.

6.2 Key indicators and reporting

RAS should be integrated into the monitoring and evaluation framework of malaria so that deployment data can be tracked with other malaria case management services. The programme objectives could be to achieve a set target coverage; and to reduce mortality among children < 6 years that might be attributable to RAS.

Key performance indicators of RAS should be metrics to be used by national programmes, health workers and other stakeholders to track and analyse factors deemed crucial to successful case management by introduction of RAS in communities. The indicators should reflect the programme processes and functions deemed most important for measuring progress towards national malaria strategic goals and performance targets.

Key indicators of the continuum of care may include recognition of illness by caretakers, recognition of severe illness by CHWs, appropriate administration of RAS, issuance of referral cards to caretakers to take to a referral health facility, completion of referral and proper management of severe malaria at referral centres (Fig. 1). The indicators are the numbers of:

- patients seen with fever and danger signs;
- patients seen with fever and danger signs given RAS;
- stock-outs of RAS when it was required during the reporting period;
- patients given RAS who were referred to a higher-level health facility; and
- patients given RAS who were referred to a higher-level health facility and received ACTs;

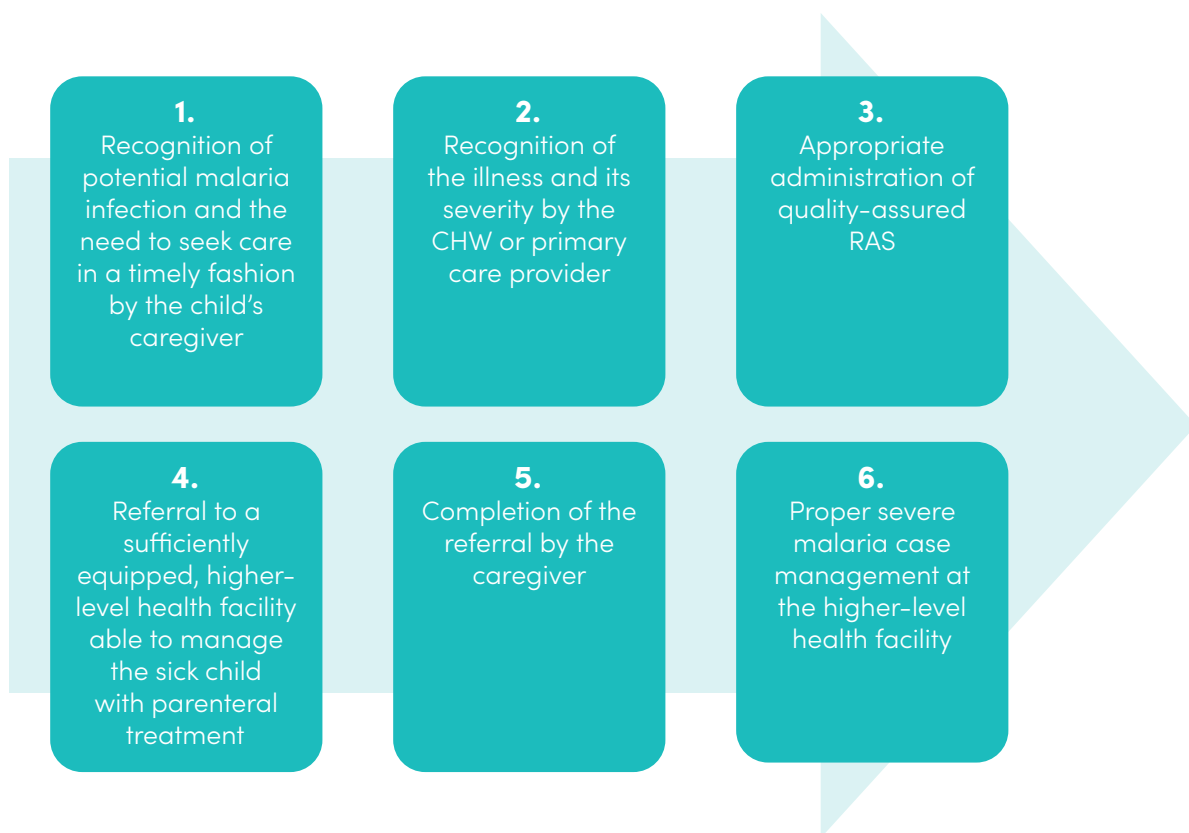
For monitoring to be successful and useful, the following elements should be in place:

- an essential RAS data point integrated into health management information systems in community health centres, peripheral facilities and referral facilities, with frequent collection, analysis and monitoring of the overall impact of malaria case management interventions;
- routine tracking of data on completion of referral and use of the information to identify gaps in the referral system that can be improved to strengthen overall case management;
- development of guidance on monitoring and evaluation, including mechanisms and the roles of various stakeholders and team members;
- promotion of operational research on RAS implementation; and
- proper feedback to front-line teams.

The reporting frequency should be stipulated and aligned with reporting of other iCCM and malaria programme indices and with reporting to the ministry of health. The indicators should be compiled by district and submitted to national level. They should be available according to the country's monitoring and evaluation plan.

Data reported by designated health facilities must be complete, timely, accurate and reproducible. The reporting channel or flow should be clearly defined. Data should be validated periodically in a data quality audit by the district health-care delivery system. A district statistician should plan for data spot checks in random facilities every reporting period and check for data completeness and accuracy.

Fig. 1. Sequence of actions for successful management of a case of severe malaria



7. Pharmacovigilance

Health personnel, CHWs and caregivers should be trained in identification and reporting of adverse events to the appropriate health facility or worker.

Pharmacovigilance is the science and activities for the detection, assessment, understanding and reporting of adverse drug reactions and other drug-related problems such as misuse, medication errors, lack of efficacy and counterfeit products. Like all medicines, RAS can cause adverse drug reactions.² In children, the most frequently reported adverse events are headache, convulsions and vomiting, although other signs can occur, such as changes in behaviour, abnormal gait, weakness, inability to sit, ringing in the ears (tinnitus), abnormal vision and speech problems. Additional side-effects, seen more often in adults, may also be seen in children, such as abdominal pain, vertigo or dizziness and double vision.

All patients receiving RAS in the community are referred to a designated referral centre to complete treatment after a single dose of RAS. RAS, like other medicines, must be subjected to the established and routine health system pharmacovigilance awareness and response. Pharmacovigilance awareness and response must be built into the training of CHWs.

² Unless a relation between an event and a drug cannot be ruled out, the event constitutes an adverse event. Designation of adverse drug reactions always implies a causal relation between the medicine and the event.

8. Monitoring of resistance

Countries should ensure continued monitoring of the therapeutic efficacy and resistance of antimalarial medicines, as recommended by WHO.

RAS is an artemisinin-based monotherapy, which requires complete treatment with injectable artesunate and a full treatment course of ACT to cure malaria. Widespread administration of artemisinin-based monotherapy, including RAS, may increase pressure and lead to the selection of *K13* mutations, which confer partial resistance to artemisinin. Mutations have been detected in several African countries (Eritrea, Rwanda, Uganda and the United Republic of Tanzania).

Therefore, it is recommended that countries:

- establish effective mechanisms for monitoring resistance to artemisinin by detection of validated *K13* molecular markers; and
- establish or strengthen collaboration among national malaria control programmes, local research institutions, WHO and other organizations involved in monitoring antimalarial drug resistance.

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1. WHO guidelines for malaria, 14 March 2023. Geneva: World Health Organization; 2023 (<https://apps.who.int/iris/handle/10665/366432>, accessed 21 July 2023).
2. Guidelines for the treatment of malaria, third edition. Geneva: World Health Organization, 2015 (<https://apps.who.int/iris/handle/10665/162441>, accessed on 21 July 2023).
3. Gomes MF, Faiz MA, Gyapong JO, Warsame M, Agbenyega T, Babiker A et al. (2009) Pre-referral rectal artesunate to prevent death and disability in severe malaria: a placebo-controlled trial. *Lancet*. 2009;373(9663):557–66. doi:10.1016/S0140-6736(08)61734-1.
4. Manual for developing national malaria strategic plans. Geneva: World Health Organization; 2019 (<https://apps.who.int/iris/handle/10665/324995>, accessed on 21 July 2023).
5. WHO guideline on health policy and system support to optimize community health worker programmes. Geneva: World Health Organization; 2018 (<https://apps.who.int/iris/handle/10665/275474>, accessed on 21 July 2023).

Annex 1. Relevant documents on integrated community case management (iCCM) of the sick child (Lilongwe, Ministry of Health of Malawi)

The documents listed below can be accessed on <https://www.health.gov.mw> under “Downloads” in the section “Preventive health services: IMCI unit”:



1. Referral note from health surveillance assistant (HSA): Sick child. Undated (<https://www.health.gov.mw/download/iccm-referral-booklet-form/>, accessed 23 June 2023).
2. Caring for the sick child in the community. Facilitator notes. 2023 (<https://www.health.gov.mw/download/caring-for-the-sick-child-in-the-community-facilitator-notes/>, accessed 7 July 2023).
3. iCCM manual for the health surveillance assistant (HAS). 2021 (<https://www.health.gov.mw/download/imci-caring-for-newborns-and-children-in-the-community-manual-for-hsas-revised/>, accessed 23 June 2023).
4. Enhanced management trainers guide: health centre staff and HSA training. 2020 (<https://www.health.gov.mw/download/enhanced-management-trainers-guide-hsa-training/>, accessed 23 June 2023).
5. Enhanced management trainers guide: district and cluster supervisor’s training. 2020 (<https://www.health.gov.mw/download/enhanced-management-trainers-guide/>, accessed 23 June 2023).
6. Enhanced management of community health products standard operating procedures. 2020 (<https://www.health.gov.mw/download/enhanced-management-of-community-health-products-standard-operating-procedures/>, accessed 23 June 2023).
7. Final iCCM supervision checklist. 2021 (<https://www.health.gov.mw/download/final-iccm-supervision-checklist/>, accessed 23 June 2023)
8. Form 1A. Village clinics monthly report form for under fives. Undated (https://www.health.gov.mw/download/form-1-b1_health-facility-hsa-monthly-reporting-form/, accessed 23 June 2023).

Annex 2. Rectal artesunate: tools and training (Severe Malaria Observatory, Medicines for Malaria Ventures – MMV)

Artesunate rectal capsules user guide. <https://www.mmv.org/access/tool-kits/artesunate-rectal-capsules-tool-kit>, accessed 23 June 2023).


Artesunate rectal capsules job aid. https://www.mmv.org/sites/default/files/uploads/docs/access/Rectal_artesunate_tool_kit/jobaid_RAS_ENG.pdf, accessed 23 June 2023).

Annex 3. Examples of posters: use rectal artesunate (RAS) to save your child (Kampala, Ministry of Health of Uganda and UNICEF)





USE RECTAL ARTESUNATE (RAS) TO SAVE YOUR CHILD

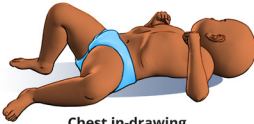
Please take your child to the VHT if they have the danger signs below




Vomiting every thing




Not able to breastfeed or drink




Chest in-drawing




Convulsions



very sleepy or unconscious




VHT inserting Rectal Artesunate



Referral completed at the facility

- RAS is effective, quick acting, safe and free of charge
- Seek early treatment from a VHT or health centre
- Adhere to the referral and treatment.

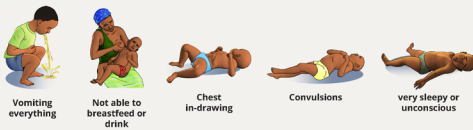
Printed with support from UNICEF and funding from UNITAID and CHAI


for every child

SAVE YOUR CHILD AND USE RECTAL ARTESUNATE (RAS)

THREE THINGS YOU NEED TO KNOW ABOUT RAS

1. RAS is a medicine given to a child with fever and one or more danger signs before referral to a higher level health facility. It is administered by inserting a capsule in the rectum.
2. RAS is administered to children aged 4 months to less than 5 years



3. RAS is not complete treatment for children with fever and one or more danger signs. Please go to the health facility as advised even when your child seems better for complete/full treatment.

THREE REASONS WHY RAS IS IMPORTANT

1. RAS allows for immediate treatment of a child with a fever and one or more danger signs when there is likely to be a delay getting the child to the health facility for complete/full treatment.
2. RAS can be used when the child is unable to use oral medication.
3. RAS is safe, fast acting, effective and free. It helps to prevent death and disability due to malaria.

WHERE CAN I GET RAS?

You can get RAS from a trained VHT or at your nearest health facility (HC II)

For further information please contact:

Global Malaria Programme
World Health Organization

20 Avenue Appia

1211 Geneva 27

Switzerland

Email: GMInfo@who.int

9789240082953

