

Monitoring and Evaluation of Pharmaceutical Management Aspects of ACT Policy Implementation: An Indicator-Based Tool



Strengthening Pharmaceutical Systems
Center for Pharmaceutical Management
Management Sciences for Health
4301 N. Fairfax Drive, Suite 400
Arlington, VA 22203 USA
Phone: 703.524.6575
Fax: 703.524.7898
E-mail: sps@msh.org

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About SPS

The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to and appropriate use of medicines.

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Management Sciences for Health
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Arlington, VA 22203 USA
Telephone: 703.524.6575
Fax: 703.524.7898
E-mail: sps@msh.org
Web: www.msh.org/sps

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This indicator-based tool was developed based on Rational Pharmaceutical Management Plus (RPM Plus) country experience helping Ministries of Health and National Malaria Control Programs in many countries transition to new antimalarial treatment therapies: artemisinin-based combination therapies. It pulls portions of text from the RPM Plus *Pharmaceutical Management for Malaria Assessment* tool and is meant to complement *Changing Malaria Treatment Policy to Artemisinin-based Combinations: An Implementation Guide*. Originally initiated under RPM Plus funding, this document was then finalized under Strengthening Pharmaceutical Systems (SPS) program funding.

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ACRONYMS

ACT	artemisinin-based combination therapy
AIDS	acquired immunodeficiency syndrome
BCC	behavior change communications
CMS	Central Medical Store
DAS	Drug Availability Study
DUS	Drug Use Study
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
HIV	human immunodeficiency virus
IEC	information, education, communication
IPT	intermittent preventive treatment
M&E	monitoring and evaluation
MOH	Ministry of Health
MSH	Management Sciences for Health
NEML	national essential medicines list
NGO	nongovernmental organization
NMCP	National Malaria Control Program
PMI	President's Malaria Initiative
RBM	Roll Back Malaria [Initiative]
RDT	rapid diagnostic test
RPM	Rational Pharmaceutical Management [Program]
SPS	Strengthening Pharmaceutical Systems [Program]
STGs	standard treatment guidelines
SUFI	scale-up for impact [concept, WHO]
USAID	U.S. Agency for International Development
WHO	World Health Organization

BACKGROUND AND PURPOSE

Because of increased resistance of malaria parasites to conventional antimalarial medicines, in 2004 the World Health Organization (WHO) recommended artemisinin-based combination therapy (ACT) for treating uncomplicated malaria.¹ Since then, a growing number of countries have adopted the policies for case management recommended by WHO,² and by May 2008, almost all countries in Africa had changed their policies to recommend ACT as the first-line treatment for malaria,³ notwithstanding the fact that some countries have yet to fully deploy the medicines in general health services.

Much of the support and activities related to changing and implementing new antimalarial policies relate to or are part of the pharmaceutical management framework. The framework emphasizes the cyclic relationships between selection, procurement, distribution, and use activities, all of which are enabled by a strong management support system. The entire framework relies on policies, laws, and regulations, which when supported by good governance, sustain the commitment to pharmaceutical supply. These activities must be coordinated to ensure that appropriate, high-quality medicines are available when patients need them.

The policy implementation process involves an array of activities that are grouped into technical components and operational components. Technical components incorporate activities pertaining to (a) medicine selection and the required regulatory changes and (b) the appropriate use of the new medicines. The operational components incorporate procurement and supply chain activities, which ensure that the new medicines are available at the points of service delivery.⁴

Central to these two components is monitoring and evaluation (M&E) throughout planning and new policy implementation. Integrating M&E into the new policy implementation process is important, so data and information generated from monitoring can be used to guide any changes in implementation strategies or reprogramming of any activities by malaria control programs, pharmacy departments, or external stakeholders. M&E is particularly important for ACTs because many countries have limited experience in their management and use.

The purpose of this indicator-based document is to provide guidance for program managers and interested stakeholders to monitor and evaluate the pharmaceutical management aspects of ACT policy implementation. The document was developed with the assumption that countries are already monitoring some or all aspects of the new policy implementation. These indicators will not only allow evaluation of interventions and external support in rolling out ACTs in country, but will also support supervision and monitoring of pharmaceutical management at health facilities and in medical stores.

¹ WHO. 2004. *Position of WHO's Roll Back Malaria Department on Malaria Treatment Policy*. Geneva: WHO.

² WHO. 2008. *World Malaria Report 2008*. www.who.int/malaria/wmr2008

³ Olumese, P. 2008. *Global Antimalarial Drug Policy Database*. Antimalarial Treatment Policies for *P.falciparum* and *P.vivax* by Country in WHO Africa Region (May 2008 Update). www.who.int/malaria/treatment

⁴ RPM Plus Program. 2005. *Changing Malaria Treatment Policy to Artemisinin-based Combination Therapy: An Implementation Guide*. Arlington, VA: Management Sciences for Health.

INTRODUCTION

In line with the global efforts of WHO's scale-up for impact (SUF⁵) concept of preventive and therapeutic malaria interventions and sustaining malaria control over time, the majority of malaria endemic countries are at some stage of scaling up the new malaria treatment policy to achieve universal coverage of the most effective antimalarial medicines. Some countries are more advanced than others.

The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) continues to provide significant financial support to malaria control programs throughout Africa. Other international donors such as the World Bank, the President's Malaria Initiative (PMI), and others also provide financial and technical support for scaling up.

Continued increases in funding for research and development of new malaria medicines and vaccines have expanded the pipeline of products. The wide array of products in the pipeline with different availability dates will require systems that can manage ongoing treatment policy change rapidly and integrate the newly available products at the global level. The indicators provided in this document could be used in monitoring the transition and implementation process of the new products at any level. They focus on the aspects of new policy implementation that relate to components of the pharmaceutical management framework. Building on the ACT implementation guide⁶ and ACT road map,⁷ both developed by RPM Plus, the approach and indicators presented in this guide have been developed based on country-level experience with the objective of being globally promoted for country-level application.

The Roll Back Malaria (RBM) M&E Reference Group has already developed a generic approach to tracking progress on policy implementation with population-based indicators.⁸ Likewise, the GFATM has developed an M&E toolkit focusing on measuring progress;⁹ however, these indicators do not address the transition to ACTs and pharmaceutical management aspects that are critical components of new malaria treatment policy implementation.

This document is divided into two main sections for monitoring and evaluating the pharmaceutical management aspects of ACT implementation. The first section, "Background Information on ACT Policy Implementation and Pharmaceutical Management Operations," provides key information on the existing structures relevant to the policy implementation process. The second section, "Process and Outcome Indicators on ACT Policy Implementation and Pharmaceutical Management Operations," provides information on the status of the implementation process based on the technical and operational components, which are the same

⁵ WHO. 2008. *The Global Malaria Action Plan for a Malaria Free World*. www.rbm.who.int/gmap/index.html

⁶ RPM Plus Program. 2005. *Changing Malaria Treatment Policy to Artemisinin-based Combinations: An Implementation Guide*. Arlington, VA: Management Sciences for Health.

⁷ Lee, E. 2004. *Road Map for Scaling Up ACTs: 2004 and Beyond*. Arlington, VA: Management Sciences for Health.

⁸ WHO (Roll Back Malaria). 2000. *Framework for Monitoring Progress & Evaluating Outcomes and Impact*. Geneva: WHO.

⁹ GFATM. 2006. *Monitoring and Evaluation Toolkit, HIV/AIDS, Tuberculosis and Malaria*. www.theglobalfund.org/documents/me/M_E_Toolkit.pdf

as those laid out in the RPM Plus ACT implementation guide.¹⁰ Please note that this list of indicators is not exhaustive; it represents a selection of indicators to guide M&E of pharmaceutical management aspects of ACT policy implementation.

Data for some indicators may be routinely available from standard malaria control program information gathering such as routine health management information system operations, the pharmaceutical management information system, activity-based monitoring and supervision, training information, epidemic detection monitoring, pharmacovigilance, RBM Initiative sentinel sites monitoring, and other special surveys (such as a multiple indicator cluster survey or the Demographic Health Survey), whereas data for other indicators may require a special survey. Deciding which information source to use will depend on each country context and type of information system and available data. Thus, the sources and the costs of collecting and processing these data must be carefully considered.

Target Audience

This guide is intended for use by health professionals who have an interest in ACT implementation and pharmaceutical management and who work primarily at the central level. The users of this document may include the following—

- National Malaria Control Program (NMCP) managers and other ACT policy implementation stakeholders who want to measure the performance of the ACT implementation and the pharmaceutical management and supply system
- Ministry of Health (MOH) decision makers, health planners, health economists, donor representatives, or experts responsible for malaria activities
- The WHO Essential Medicines Program staff in Africa, Asia, and Latin America and the Caribbean
- Social scientists and health project or facility managers who are interested in malaria operational research and management tools

Using and Adapting the Document

Reviewing the current antimalarial treatment policy and adapting the guide to collect data for appropriate indicators to answer questions from NMCP, the Central Medical Store (CMS) and other partners will be important. Specifically, adaptors will need to review and modify the indicators and data to be collected according to the specific country situation and data needs.

NMCP managers or other stakeholders using this indicator-based tool will need to confer with CMSs and other in-country RBM partners to determine the most appropriate time to conduct an

¹⁰ RPM Plus Program. 2005. *Changing Malaria Treatment Policy to Artemisinin-based Combinations: An Implementation Guide*. Arlington, VA: Management Sciences for Health.

assessment. Depending on the data to be collected at the different levels of the system including central and regional levels and health facility and retail pharmaceutical outlets, a special survey may be required, as was previously mentioned. Please refer to RPM Plus's *Pharmaceutical Management for Malaria Manual*¹¹ for detailed guidelines on planning such an assessment or survey, a sampling methodology, and guidance on training data collectors.

¹¹ RPM Plus Program. 2004. *Pharmaceutical Management for Malaria Manual*. Arlington, VA: Management Sciences for Health. (Prepared by Malcolm Clark 2002 and revised by Rima Shretta 2003.)

BACKGROUND INFORMATION ON ACT POLICY IMPLEMENTATION AND PHARMACEUTICAL MANAGEMENT OPERATIONS

Background information on MOH pharmaceutical management operations will provide key information on the pharmaceutical management system for antimalarial medicines. To efficiently carry out the assessment, including interpreting the results and making recommendations for ACT policy implementation and for pharmaceutical management and supply system improvement, a good understanding of current pharmaceutical management operations is essential.

The background questions in table 1 provide qualitative information on the basic structures that are considered necessary for implementing an ACT policy. The questions check whether the basic structures, systems, and mechanisms under each key component exist in the country. Assessment coordinators should collect and record these data, which may be obtained at the central level, at the outset of the work. (See annex 1, “Background Information Questionnaire.”)

Table 1. Background Information on ACT Policy Implementation and Pharmaceutical Management Operations

Area or Question	Comments
Planning and Coordination	
1. Were all in-country RBM stakeholders involved in consensus-building of the analysis and appraisal of antimalarial replacement options?	Relevant stakeholders include those who are involved in the procurement, management (central or regional stores), or distribution of ACTs (e.g., NMCP, CMS, Regional Medical Store, GFATM principal recipients, WHO, and implementing partners responsible for management of medicine and service delivery).
2. Has a diagram showing system of pharmaceutical procurement and distribution for malaria medicines been drawn?	The diagram should also include the offices responsible for managing procurement of malaria products (by both purchase and donation), storage facilities, and health facilities.
Financing and Resource Mobilization	
3. Have system(s), if any, to recover the cost of the ACTs dispensed in MOH facilities been identified?	
4. Has a list been made of sources of malaria medicines flowing through the distribution system, along with estimated values for each source, including budgets and contributions of donors and nongovernmental organizations (NGOs)?	This information may be readily available from the NMCP; however, in some cases it may be more difficult to get and require some investigation.
5. For donor-supplied ACTs distributed through the CMS system, what agreements were reached to cover the storage and distribution costs to manage ACTs within this system?	Specifying whether the agreements were oral or written is important.

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Technical Considerations	
6. Is the antimalarial policy change process open to ongoing review and updating to include newly approved ACTs and antimalarial medicines as they become available?	For example, is there dynamism with respect to changing, researching, and approving new ACTs as they come available?
7. Have the malaria standard treatment guidelines (STGs) been revised to include ACTs?	If the response is yes, request a copy of the document.
8. Are the new antimalarial medicines (i.e., ACTs) listed in the revised STGs registered for use?	
9. What percentage of antimalarial medicines listed in the revised STGs are on the latest national essential medicines list (NEML)?	This percentage is calculated by dividing the total number of antimalarial medicines in the revised STGs found in the NEML by the total number of antimalarial medicines in the NEML.
10. Are the regulations regarding distribution (i.e., dispensing) and use of ACTs consistent with the national malaria treatment policy?	For example, if according to the national policy, ACTs are to be distributed at the community level have they been deregulated so practitioners other than a pharmacist, doctor, or nurse can dispense them?
11. What percentages of MOH health care providers have received training on the latest malaria STGs?	Probe into the delay between when trainings were carried out and when ACTs were made available in districts. Anecdotal evidence has shown that when the gap between training and ACT availability is large, prescribers forget some aspects of the new treatment policy.
12. Is a communication strategy or plan in place to inform the population of the new malaria treatment policy?	If the response is yes, request a copy of the document.
Operational Considerations	
13. Was an ACT implementation plan developed?	If the response is yes, given that it outlines different partner roles and responsibilities with respect to ACT implementation, the interviewer should ask about stakeholder involvement in the implementation plan development.
14. Is the ACT policy being implemented according to the implementation plan?	Ask this question just to get a sense from the NMCP on whether ACT policy rollout has been nationwide or if it has been a gradual process. Furthermore, determining the coverage of the new policy (i.e., percentage of districts implementing the ACT policy) would be useful.
15. Is an ACT tracking system in place?	
16. Were all relevant stakeholders involved in quantification of ACTs?	See number 1 above.
17. Is a written procurement plan for ACTs in place?	
18. Was a detailed distribution plan, which includes the distribution strategy and partners responsibilities, developed for ACTs?	If the response is yes, request a copy of the plan.

Background Information on ACT Policy Implementation and Pharmaceutical Management Operations

19. What are the number and distribution of MOH facilities (i.e., hospitals, health facilities, pharmacies, and depots or warehouses), pharmaceutical retail outlets, wholesalers, distributors, and manufacturers?	This information determines the number and location of facilities. The information should be available from the pharmacy department or the regulatory authority.
20. Do you have written procedures for stock management?	If the response is yes, request a copy of the procedures or plan.
21. Is a policy or plan in place to manage soon-to-expire or already-expired medicines?	
22. Is an adverse drug reaction (ADR) reporting system in place?	

PROCESS AND OUTCOME INDICATORS ON ACT POLICY IMPLEMENTATION AND PHARMACEUTICAL MANAGEMENT OPERATIONS

Selected indicators (process and outcome) have been provided in this document to assess the status of ACT policy implementation as well as the effectiveness of the implementation plan with respect to pharmaceutical management. The list of indicators (see table 2) includes indicators to assess the progression and end-result of planning and coordination, financing, and the technical and operational actions achieved including the dissemination of the new policy, ACT availability, diagnosis capacity, and the availability of rapid diagnostic tests (RDTs), storage practices, and rational use and coverage of ACTs together with the level or levels at which they should be collected. Data on indicators should be collected at the appropriate level of the health system—some data should be collected at all levels, and other data will need to be collected only at one or two levels. Both process and outcome indicators are used.

- Process indicators assess the performance (i.e., efficiency and effectiveness) of the existent structures, systems, and mechanisms. They provide quantitative information on the mechanisms and activities by which an ACT policy is implemented. These indicators are measured by a percentage (e.g., percentage change over time or percentage of coverage).
- Outcome indicators provide quantitative information on the achievement of the appropriate management and use of ACTs, an essential objective of all malaria control programs and aimed at reduction of malaria morbidity and mortality while minimizing the development of resistance.

The indicators will provide national and international audiences with a measure of the efficiency of the pharmaceutical management components of ACT policy implementation and will help in the evaluation of the effectiveness of implementation strategies.

Table 2. Core M&E Indicators for Pharmaceutical Management Aspects of ACT Policy Implementation

Indicator	Indicator Type	Health System Level	Frequency
Technical Considerations			
<i>Revision of Medicine Regulation and Registration of ACTs</i>			
1. Proportion of ACTs registered with guidance from a scientific committee	Process	Central	Annually
2. Number of antimalarial medicines other than those listed in the STGs sold in (a) public and (b) private facilities	Outcome	Facility and outlet	Annually
<i>Dissemination of Revised STGs and Other Relevant Guidelines</i>			
3. Percentage of health facilities that have a copy of the most recent STGs for malaria	Process	Facility	Quarterly

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Indicator	Indicator Type	Health System Level	Frequency
<i>Training and Supervision of Health Workers Consistent with the New Guidelines</i>			
4. Ratio of confirmed malaria cases (according to national policy) by age group to treatments dispensed for a defined review period by level of care ¹²	Outcome	Facility	Quarterly
5. Percentage of encounters with patients diagnosed with uncomplicated malaria who are prescribed an antimalarial medicine consistent with latest national STGs at (a) MOH health facilities and (b) retail pharmaceutical outlets	Outcome	Facility and outlet	Annually
<i>Information, Education, and Communication (IEC) Targeting Providers and the Community</i>			
6. Percentage of health facilities with IEC materials and job aids related to ACTs	Process	Facility	Annually
7. Percentage of patients or caregivers who could correctly describe how to take or give the prescribed antimalarial medicine	Outcome	Facility	Annually
8. Percentage of encounters at (a) MOH health facilities and (b) private facilities at which health care staff members explained the dose and frequency of the prescribed medicines to the patient or caregiver	Outcome	Facility and outlet	Annually
Operational Considerations			
<i>Forecasting of Demand and Quantification</i>			
9. Percentage of staff doing quantification who have received training in the past year	Process	Central	Annually
10. Percentage of MOH health facilities recording ACT consumption data according to directions	Process	Facility	Quarterly
<i>Procurement</i>			
11. Percentage of complete ACT shipments received on time according to the delivery schedule	Outcome	Central	Quarterly, biannually
12. Percentage of items received for which the minimum shelf life equaled or exceeded the shelf life specified on the purchase order	Process	Central	Annually
<i>Distribution</i>			
13. Percentage of facilities that received on-time deliveries within the past three months	Process	Regional and facility	Quarterly
<i>Inventory Management</i>			
14. Average percentage of time out of stock for a set of antimalarial medicines and supplies, as specified in the latest national STGs, in MOH storage and health facilities during the last 12 months or since implementation	Outcome	Central, regional, and facility	Annually

¹² This ratio depends on the country's malaria treatment policy; WHO recommends all children under five presenting with symptoms of fever be treated presumptively for malaria.

Process and Outcome Indicators on ACT Policy Implementation and Pharmaceutical Management Operations

Indicator	Indicator Type	Health System Level	Frequency
15. Average percentage of stock records that correspond with physical counts for new antimalarial medicines listed in the latest STGs in MOH storage and health facilities	Outcome	Central, regional, and facility	Quarterly
Review of Quality Assurance Mechanisms			
<i>Pharmacovigilance</i>			
16. Percentage of health facilities that have procedures in place to report ADRs associated with ACTs	Process	Central and facility	Annually
<i>Product Quality Surveillance</i>			
17. Percentage of ACT shipments received in the past 12 months that have been rejected based on quality issues (i.e., poor or substandard quality or that do not meet quality standards)	Outcome	Central	Annually
18. Percentage of samples of circulating ACT stocks that were tested in the past 12 months and found to be substandard	Outcome	Central	Annually

Detailed descriptions of these indicators, including definition, rationale, where to collect the related data, and with which stakeholders to discuss as well as how to calculate the indicator, can be found in annex 2. Annex 3 contains related collection forms.

4. List sources of malaria medicines flowing through the distribution system and estimated values for each source, including budgets and contributions of donors and NGOs [for the past 12 months].

Antimalarial Medicine	Source(s)	Estimated Value	Budget	Value Contributed by Donors

5. Have there been any agreements to cover the storage and distribution costs to manage donor-supplied ACTs that are being distributed through the CMS system?

(1) Yes → What are the arrangements?

(2) No

Section C. Technical Considerations

6. Is the antimalarial medicine policy change process open to ongoing review and updating to include newly approved ACTs or antimalarial medicines as they become available?

(1) Yes → In what way?

(2) No

7. Have the malaria STGs been revised to include ACTs?

(1) Yes → Seen
Not seen

Please indicate the date of the most recent revision

(2) No

8. Are the new antimalarial medicines (i.e., ACTs) listed in the revised STGs registered for use?

(1) Yes → Indicate product name and registration status (include provisional registration)

(2) No

9. List antimalarial medicines found in the revised STGs and latest NEML.

Product Name	In the Revised STGs? (Yes/No)	In the Latest NEML? (Yes/No)

10. Are the regulations regarding distribution (i.e., dispensing) and use of ACT consistent with the national malaria treatment policy?

(1) Yes

(2) No → Explain the inconsistency.

11. Number of MOH health care providers who have received any training on the new malaria STGs.

Number trained _____ Number not trained _____
 Coverage _____

Were trainings conducted before or after ACTS were made available ?

(1) Before

(2) After

(3) Other. Explain _____

12. Is a communication strategy or plan in place to inform the population of the new malaria treatment policy?

(1) Yes → Seen
 Not seen

(2) No

Section D. Operational Considerations

13. Was an ACT implementation plan developed?

- (1) Yes → Seen
Not seen

List partners involved in the development and their roles

- (2) No

14. Is the ACT policy being implemented according to the implementation plan?

- (1) Yes

→ Number of districts where implementation is according to plan _____

→ Number of districts where the ACT plan has not been implemented yet

→ Total number of districts _____

- (2) No

15. Is a system or written procedures for tracking ACT in place?

- (1) Yes → Seen
Not seen

- (2) No

16. List stakeholders who have been involved in quantification of ACTs and their role in process.

21. Is a policy or plan in place to manage soon-to-expire or already-expired medicines?

(1) Yes → Seen
Not seen

(2) No

22. Do you have written procedures or systems for reporting ADRs?

(1) Yes → Seen
Not seen

(2) No

ANNEX 2. INDICATOR DESCRIPTIONS

Indicator Description Format

Annex 2 presents detailed descriptions for each indicator. Each description follows exactly the same format, which is summarized below.

Definition, rationale, and interpretation	The meaning of the indicator and the terms used to describe the indicator as well as the reason the indicator is important
Suggested data source	The most likely and suggested sources of information, particularly where the data are to be collected and what documents and records to review
Stakeholders to interview	The most likely and suggested sources of information in terms of which stakeholders to ask for assistance and interview
Frequency	The suggested frequency of monitoring for the indicator
Type of indicator	The type of indicator, for example, input, process, output, outcome, or impact
Calculation	The numerator and denominator and how to calculate the indicator if necessary
Data collection form	The data collection form(s) to be used to collect data for this indicator
Notes and caveats	Any additional notes or caveats to consider related to the indicator

Technical Considerations

The technical considerations indicators (i.e., numbers 1 through 8) incorporate activities related to the regulation and appropriate use of the medicines through development and dissemination of guidelines and the development and use of appropriate training and behavioral change communication (BCC) strategies.

Revision of Medicine Regulation and Registration of ACTs

Regulatory changes are necessary for successful implementation of a new pharmaceutical policy, including registration. New antimalarial medicines must be authorized for sale within the country. Many countries have registration procedures to ensure that approved products are of good quality and are safe and efficacious. Pharmaceutical classification or scheduling¹³ is another regulatory process that follows the new policy recommendations and STGs. Pharmaceutical classification or scheduling must be determined to ensure availability of new antimalarial therapies at public and private health facilities is consistent with the new policy treatment with respect to dispensing treatment. Indicators 1 and 2 address regulation and registration.

¹³ This designation refers to the legal status of a medicine (e.g., prescription-only medicine, over-the-counter medicine).

1. Proportion of ACTs registered with guidance from a scientific committee

Definition, rationale, and interpretation	Measures the proportion of ACTs that are registered with guidance from a scientific committee. A decision to choose one treatment over another should be guided by evidence of its therapeutic efficacy in the country.
Suggested data source	Registrar of medicines
Stakeholders to interview	Department of Pharmacy and Medicines; National Drug Regulatory Authority; Food and Drugs Board; NMCP
Frequency	Annually
Type of indicator	Process
Calculation	<u>Numerator</u> : Number of antimalarial medicines registered with guidance from a scientific committee <u>Denominator</u> : Total number of antimalarial medicines registered
Data collection form	Central- or national-level questionnaire
Notes and caveats	Some countries may rely on therapeutic efficacy studies from other countries

2. Number of antimalarial medicines other than those listed in the STGs that are sold in (a) public and (b) private facilities

Definition, rationale, and interpretation	The successful implementation of the new policy is dependent on the availability of recommended medicines in either public or private sectors coupled with the phasing out of older treatments. This indicator will determine the total number of all antimalarial medicines not listed in STGs to guide the phasing-out process. Data collectors will determine which antimalarial medicines are in stock at each visited facility. Available antimalarial medicines should be noted on provided data collection forms.
Suggested data source	Health facilities (public and private); pharmaceutical outlets
Stakeholders to interview	Health facility staff; medicine sellers
Frequency	Annually
Type of indicator	Outcome
Calculation	Sum of all other antimalarial medicines than those listed in the STGs sold in public and private facilities
Data collection form	Drug Availability Study (DAS) 1
Notes and caveats	Legislative changes to remove or ban the use of monotherapies can require a long time to take effect depending on the country context and the process required for instituting such a change.

Dissemination of the Revised STGs and Other Relevant Guidelines

STGs are disease specific, they reflect a consensus on the first-line treatment of choice and alternative treatments for the disease in question. Once the new medicine policy has been agreed upon, the STGs must be revised. In addition a plan must be developed for the dissemination of the revised STGs to both public and private sectors. Indicator 3 relates to dissemination of revised STGs in the public sector

3. Percentage of health facilities that have a copy of the most recent STGs for malaria

Definition, rationale, and interpretation	Measures the level of dissemination and availability of the most recent malaria STGs at health facilities to help health care providers appropriately diagnose and treat malaria
Suggested data source	Presence of STGs at health facilities at all levels of the system
Stakeholders to interview	Health facility staff
Frequency	Quarterly
Type of indicator	Process
Calculation	<i>Numerator:</i> Number of MOH health facilities that have a copy of the most recent STGs for malaria <i>Denominator:</i> Total number of MOH health facilities surveyed
Data collection form	Drug Use Study (DUS) 1
Notes and caveats	The document presented as STGs should— <ul style="list-style-type: none">• Be intended as a clinical reference for health care providers• Present information on examination and treatment (including pharmaceutical therapy)

Training and Supervision of Health Workers Consistent with the New Guidelines

Dissemination of STGs should be coupled with sensitization and training of the health workers on the new guidelines. Trainings and sensitizations are most effective when done shortly before the new treatment is available. This timing may not be possible in many countries, however, given several limitations in implementing trainings, so enforcing the trainings and supporting the new treatment implementation through regular supervision visits to facilities is important. Indicators 4 and 5 address training and supervision of health workers in both the public and private sectors.

4. Ratio of confirmed malaria cases (according to national policy) by age group to treatments dispensed for a defined review period by level of care

Definition, rationale, and interpretation	Measures the number of confirmed malaria cases in relation to the number of treatments dispensed. With the increased cost of ACTs, reducing the amount of over-diagnosis of malaria through use of confirmatory tests such as microscopy and RDTs is important.
Suggested data source	Health facility and retail outlet reports; data collected during supervision visits
Stakeholders to interview	Health facility staff (and private sector staff) responsible for health consultations and diagnosis
Frequency	Quarterly
Type of indicator	Outcome
Calculation	<u>Numerator</u> : Number of confirmed malaria cases by age group <u>Denominator</u> : Total treatments dispensed by age group
Data collection form	DUS-1
Notes and caveats	This indicator is most interesting in the case of countries using RDTs for diagnosis among either the general population or a subgroup. This indicator is applicable at the level of care where it is required to confirm malaria cases (e.g., some countries do not require malaria confirmation at the primary care or community level).

5. Percentage of encounters with patients diagnosed with uncomplicated malaria who are prescribed an antimalarial medicine consistent with the latest national STGs at (a) MOH health facilities and (b) retail pharmaceutical outlets

Definition, rationale, and interpretation	Measures the degree of adherence to national STGs for malaria. Following STGs to treat uncomplicated malaria is essential if health care workers are to reduce costs, improve health outcomes, and reduce the risk of contributing to the development of drug resistance.
Suggested data source	Uncomplicated malaria cases should be diagnosed and confirmed according to methods outlined in the STGs. Daily health register; patient medical records and prescription slips; direct observation of consultations and simulated purchase
Stakeholders to interview	Health facility manager; pharmacy dispenser
Frequency	Annually
Type of indicator	Outcome
Calculation	<u>Numerator</u> : Number of encounters with patients who have been diagnosed with uncomplicated malaria and who are prescribed an antimalarial medicine consistent with the latest STGs <u>Denominator</u> : Total number of prescriptions for uncomplicated malaria in sample
Data collection form	DUS-1, DUS-2, DUS-3, DUS-4
Notes and caveats	Obtain permission to review records in public health system; in private facilities, conduct simulated purchases.

IEC Targeting Providers and the Community

Implementing a new treatment policy must also be coordinated with developing behavioral change and capacity-building strategies to ensure that the same messages are communicated to health care workers at all levels and the public in general. Providers must also be able to explain the appropriate use of the new treatments to their clients. Indicators 6–8 relate to the dissemination of BCC materials as well as the level of communication between patients and providers.

6. Percentage of health facilities with IEC materials and job aids related to ACTs

Definition, rationale, and interpretation	Measures the level of dissemination of communication materials of the new policy to promote acceptance and use of the new malaria treatments
Suggested data source	Observed BCC materials and job aids at health facilities at all levels of the system
Stakeholders to interview	Health facility staff; observation
Frequency	Annually
Type of indicator	Process
Calculation	<u>Numerator</u> : Number of MOH health facilities with IEC materials and job aids related to ACTs <u>Denominator</u> : Total number of MOH health facilities surveyed
Data collection form	DUS-1
Notes and caveats	BCC materials and job aids are required to reinforce the implementation of the new policy among health workers and reassure health workers of the efficacy of the new treatments.

7. Percentage of patients or caregivers who could correctly describe how to take or give the prescribed antimalarial medicine

Definition, rationale, and interpretation	Measures the effectiveness of the communication between the health care provider and the patient. The indicator also measures the potential for nonadherence and possible treatment failure because of a lack of knowledge of patients and caregivers on how to administer the antimalarial medicine correctly.
	The patient or caregiver should be able to correctly describe the dose of the medicine, how many times a day it should be taken or administered, for how many days, and how it should be administered.
Suggested data source	Patient knowledge of how to administer antimalarial medicine from health facility exit poll interviews
Stakeholders to interview	Malaria patients or caregivers of malaria patients
Frequency	Annually
Type of indicator	Outcome
Calculation	<u>Numerator</u> : Number of antimalarial medicines dispensed for which the patient or caregiver could correctly recall the dose, frequency, and duration of the medicines <u>Denominator</u> : Total number of antimalarial medicines dispensed to patients or caregivers interviewed
Data collection form	DUS-3
Notes and caveats	Obtain permission from the health facility to conduct exit poll interviews with malaria patients and caregivers.

8. Percentage of encounters at (a) MOH health facilities and (b) private facilities at which health care staff members explained the dose and frequency of the prescribed medicines to the patient or caregiver

Definition, rationale, and interpretation	<p>Measures the health care provider’s ability to effectively communicate to patients how to administer the prescribed antimalarial medicines. This ability is an important aspect of understanding patient use of medicines and patient education.</p> <p>The minimum information the health care staff members should provide to patients and caregivers covers the dose, frequency, and duration of antimalarial medication use. Additional information could include how to prepare the medicine, whether to take the medicine with food, and any potential side effects or symptoms associated with the medicine. If the health care provider explains at least the minimum information to the patient or caregiver for this indicator, however, he or she has provided information regarding the prescribed antimalarial medicine. Failure to directly discuss the dose, frequency, and duration of antimalarial medicine use with the patient or caregiver will be considered as not providing any information.</p>
Suggested data source	Patient consultation observations in public health facilities and simulated purchases in private retail pharmaceutical outlets
Stakeholders to interview	Health care provider, prescriber, or dispenser; simulated purchase
Frequency	Annually
Type of indicator	Outcome
Calculation	<p><u>Numerator</u>: Number of encounters at which health care staff members explained the dose, frequency, and duration of antimalarial medicine use to the patient or caregiver</p> <p><u>Denominator</u>: Total number of encounters where health care staff members dispensed antimalarial medicines to patients or caregivers</p>
Data collection form	DUS-2, DUS-4
Notes and caveats	Obtain permission from the health facility to observe patient consultations.

Operational Considerations

Operational considerations indicators (i.e., numbers 9 through 15) include activities related to procurement and supply management, which ensure that the new medicines (i.e., ACTs) are available for use.

When a first-line treatment is changed, developing a plan to phase out the previous first-line antimalarial is essential during the transition phase to avoid wastage when the new policy is implemented. Large pipelines of outdated medicines in the system can cause a reluctance to change treatments. In-country partners must also agree upon how the new policy will be implemented. The new policy can be implemented in a phased approach, for example a gradual implementation of the new treatment through selected regions, districts, or levels of the health system, or through nationwide rollout, where the treatments would be made available across the country at the same time. The decision on which method to use has implications for many other aspects of ACT implementation.

Forecasting of Demand and Quantification

Forecasting of demand and quantifying antimalarial needs can be challenging, complex, and time consuming. Several different methods can be used to estimate antimalarial medicine needs, and each method requires certain data. These data include malaria morbidity or antimalarial medicine consumption, which can be difficult to obtain or incomplete, making the quantification exercise more difficult. Additionally, biological confirmation of malaria and other malaria interventions, and their effect on future malaria transmission and incidence as well as other malaria prevention strategies such as indoor residual spraying campaigns and insecticide-treated net distribution will affect the quantities of antimalarial medicines to be procured and need to be considered in forecasting malaria medicine needs for the long-term. Indicators 9 and 10 address forecasting.

9. Percentage of staff doing quantification who have received training in the past year

Definition, rationale, and interpretation	Measures the proportion of staff trained in doing quantifications. Individuals involved in quantification must be well informed on using available data and assumptions to estimate needs. This team is essential to avoid gaps or overstocks of ACT availability.
Suggested data source	NMCP; MOH procurement unit; other donors or partners involved in procuring antimalarial medicines
Stakeholders to interview	NMCP; MOH procurement unit; procurement partners
Frequency	Annually
Type of indicator	Process
Calculation	<u>Numerator</u> : Number of staff trained on quantification among the quantification team <u>Denominator</u> : Total number of quantification team members
Data collection form	Central- or national-level questionnaire
Notes and caveats	In some countries, quantifications are done by a designated committee. Data collectors will have to find out if this is the case.

10. Percentage of MOH health facilities recording ACT consumption data according to directions

Definition, rationale, and interpretation	Measures the level of accuracy in recording ACT consumption at intermediate depot and health facility levels. Data collectors will review recorded ACT consumption data compared to how the ACT tracking system guides what and how data will be recorded and reported. Monitoring the accuracy of data reported in the ACT tracking system will be important; therefore periodic verification of data accuracy will be necessary. This verification will ensure data quality, which is always a question at higher levels when data are being used for decision making.
Suggested data source	Health facility reports and bin cards; registers
Stakeholders to interview	Health facility manager or pharmacist
Frequency	Quarterly
Type of indicator	Process
Calculation	<i>Numerator:</i> Number of health facilities accurately recording ACT consumption data according to directions <i>Denominator:</i> Total number of health facilities surveyed
Data collection form	DAS-2
Notes and caveats	Whenever possible, data collectors should cross-check the actual stock count at the facility.

Procurement

The primary purpose of procurement is to provide regular delivery of adequate quantities of high-quality supplies at the lowest cost. National procurement decisions take place within a country's policy and legal framework and may take place at the central level or be decentralized down to the lower levels. Many countries are procuring ACTs using donor funds (e.g., GFATM, PMI, or World Bank), so other partners and stakeholders may be involved in the procurement process as well as additional regulations. For the purposes of this assessment, the focus will be on procurement for the public sector. Indicators 11 and 12 address procurement.

11. Percentage of complete ACT shipments received on time according to the delivery schedule

Definition, rationale, and interpretation	Measures the reliability of the ACT supplier in delivering products in a timely manner based on a previously established delivery schedule
Suggested data source	MOH procurement unit records; port receipt logs; CMS receipt logs
Stakeholders to interview	MOH procurement unit; port manager; CMS manager; warehouse manager
Frequency	Quarterly or biannually (depending on delivery schedule)
Type of indicator	Outcome
Calculation	<i>Numerator:</i> Number of ACT shipments received completely and on time based on the delivery schedule <i>Denominator:</i> Total number of ACT shipments received
Data collection form	Central- or national-level questionnaire
Notes and caveats	ACT consignments are likely to be staggered throughout the year (as opposed to one or two annual deliveries) due to their packaging, which makes them more bulky, and the storage limitations in many countries.

12. Percentage of items received for which the minimum shelf life equaled or exceeded the shelf life specified on the purchase order

Definition, rationale, and interpretation	Determines whether shelf life regulations in a country are adhered to. Given the short shelf span of ACTs, keeping track of shelf lives of all received products is important to reduce the risk of having expired or near expired stocks.
Suggested data source	Shelf life regulations; purchase orders; shipment invoices,
Stakeholders to interview	MOH procurement unit; CMS manager; warehouse manager
Frequency	Annually
Type of indicator	Process
Calculation	<i>Numerator:</i> Number of items received for which the minimum shelf life equaled or exceeded the shelf life specified on the purchase order <i>Denominator:</i> Total number of items received
Data collection form	Central- or national-level questionnaire
Notes and caveats	Review the minimum shelf regulation in the country.

Distribution

Distribution (indicator number 13) covers how medicines are issued and transported within the health system through the different levels (i.e., central, regional or provincial, district, facility) so that they are available at service delivery points. Sometimes the distribution system for antimalarial medicines is a parallel system that is managed by the NMCP or other procurement stakeholders. In the case of ACTs, the hygroscopic nature of the medicines as well as their short shelf life and bulky packaging are important factors that affect their distribution. As such, an effective distribution system is critical to avoid loss due to expiry or damage, particularly since ACTs are significantly more costly than chloroquine or sulfadoxine-pyrimethamine.

13. Percent of facilities that received on-time deliveries within the past three months

Definition, rationale, and interpretation	Measures the proportion of facilities receiving supplies in a timely manner. This indicator assumes an established delivery schedule.
Suggested data source	Delivery schedules; transaction records stock cards
Stakeholders to interview	Regional or District Medical Store manager; facility in charge
Frequency	Quarterly
Type of indicator	Process
Calculation	<i>Numerator:</i> Total number of facilities that received on-time deliveries for a scheduled order within the past three months <i>Denominator:</i> Total number of facilities visited
Data collection form	DAS-2
Notes and caveats	

Inventory Management

Storage and distribution include all activities related to managing an inventory, including ordering, receiving, storing, issuing, and reordering supplies. These activities take place at pharmaceutical storage facilities at various levels of the system. The goals of inventory management are to protect stored items from loss, damage, theft, or wastage and to manage the reliable movement of supplies from source to user in the least expensive way. In the case of ACT inventory management (as with distribution), storage and inventory control are particularly important due to the hygroscopic nature of the medicines as well as their short shelf life and bulky packaging. Therefore the performance of the inventory management system is critical to avoid loss due to expiry, damage, theft, or leakages that are preventable through effective management practices. Indicators 14 and 15 address inventory management.

14. Average percentage of time out of stock for a set of antimalarial medicines and supplies, as specified in the latest national STGs, in MOH storage and health facilities during the last 12 months or since implementation.

Definition, rationale, and interpretation Measures the procurement and distribution systems' performance in maintaining an uninterrupted supply of medicines and supplies. Successful ACT implementation depends on a constant supply of these medicines.

If diagnosis of malaria is to be confirmed using RDTs, then the supply of RDTs will need to be adequate to cover all patients presenting with symptoms consistent with malaria. Use of RDTs can be effective in reducing the over-diagnosis that is common with clinical diagnosis of malaria, though they are likely more useful in zones of lower endemicity or unstable transmission than in highly endemic zones.

Suggested data source CMS stock records; regional depot stock records; health facility stock records; private retail pharmaceutical stock records (if any)

Stakeholders to interview CMS staff; regional depot staff; health facility pharmacy staff; private retail pharmacy staff

Frequency Annually

Type of indicator Outcome

Calculation
Numerator: Total number of days out of stock for a set of antimalarial medicines and supplies normally stocked
Denominator: 365 × the total number of antimalarial medicines and supplies normally stocked
Example: The following is a list of antimalarial medicines normally stocked at the central medical store.

Product	Total Number of Days Out of Stock
Artemether-lumefantrine 20/120 mg tablets (pack size 2)	36
Sulfadoxine-pyrimethamine 500 mg/25 mg tablets	64
Quinine injection 40 mg/ml	123

Average percentage of time that a set of antimalarial medicine were out of stock =

$$\frac{(36 + 64 + 123) \times 100}{365 \times 3} = 20\%$$

In this example, over a 12-month period, antimalarial medicines were out of stock an average of 20 percent of the time at the CMS.

Data collection form DAS-3
Notes and caveats The same calculation can be applied at the regional or facility level or at a sample of facilities.

15. Average percentage of stock records that correspond with physical counts for new antimalarial medicines listed in the latest STGs in MOH storage and health facilities

Definition, rationale, and interpretation Measures the quality of the stock record-keeping system in storage and health facilities; measures how far off physical counts are with theoretical stock counts according to stock records. This indicator will help reveal inventory management problems such as wastage, pilferage, and poor record-keeping, all of which contribute to poor service delivery and financial losses. Additionally, inaccuracies between the theoretical and actual stock counts can result in delayed ordering and possibly stock-outs.

Suggested data source CMS, regional depot, and health facility stock records and physical counts

Stakeholders to interview CMS inventory officer or storekeeper; regional depot manager; health facility dispenser or pharmacy staff

Frequency Quarterly

Type of indicator Outcome

Calculation **Step 1.** Calculate the absolute percentage difference for each product in the set.

Numerator: Absolute difference between quantity of stock on hand as determined by physical inventory and quantity of stock on hand as recorded on stock card

Denominator: Quantity of stock on hand as recorded on stock card

Step 2. Calculate the average percentage difference for all products in set.

Numerator: Sum of absolute percentage differences calculated in step 1

Denominator: Total number of products in set

Example Assume the following list of antimalarial medicines—

Product	Record	Count
Artemether-lumefantrine 20/120 mg tablets (Pack size 2)	10,000	10,000
Sulfadoxine-pyrimethamine 500 mg/25 mg tablets	1,000	990
Quinine tablets 300 mg	88	87

To calculate the percentage of stock records that correspond exactly with physical counts, perform the following steps:

For one health facility, using antimalarial medicine list above—

1. The number of records examined = 3
2. The number of records with no discrepancy = 1
Percentage of stock records corresponding with physical stock counts = $\frac{1}{3} \times 100 = 33\%$

For a sample of 20 health facilities, for which the sum of percentages of stock records that correspond exactly with physical counts is 600 percent, the average percentage of antimalarial medicines that correspond exactly with physical counts is calculated as—

$$\text{Average percentage of stock records corresponding with physical count} = \frac{600\%}{20} = 30\%$$

The average percentage of health facility records that corresponded exactly with physical counts was 30 percent.

Data collection form

DAS-2

Notes and caveats

All pack sizes and presentations should be included separately for this indicator.

Ask staff to produce the most accurate records of current ACT stock levels and note the means used to produce these estimates (i.e., computerized system, manual ledgers, bin cards). Ask staff to produce records for any recent stock receipt and issue figures and update the stock records accordingly.

Review of Quality Assurance Mechanisms

To ensure an uninterrupted supply of antimalarial medicines of assured quality, appropriate quality assurance mechanisms must be in place and functioning. The purpose of quality assurance in public pharmaceutical supply systems is to make certain that each medicine reaching a patient is safe, effective, and of standard quality.¹⁴ At several points within the pharmaceutical management framework, taking particular care is required to ensure that the medicines' quality is confirmed and that conditions are such that the quality is maintained until the point at which the medicine is dispensed to the patient. Once a medicine is dispensed, having a system to monitor ADRs is also important. Indicators 16 through 18 address these issues of quality-assurance mechanisms.

Pharmacovigilance

Pharmacovigilance encompasses the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible medicine-related

¹⁴ MSH and WHO. 1997. *Managing Drug Supply*. 2nd ed. West Hartford, CT: Kumarian Press (Chapter 18. Quality Assurance for Drug Procurement, p. 272).

problems.¹⁵ Accordingly, the goal of pharmacovigilance is to safeguard public health and improve rational medicine use through efficient and timely collection, assessment, and communication of risks and benefits to support local decision making.¹⁶

Since ACTs are new treatment therapies, countries must monitor ADRs associated with the use of these antimalarial medicines. Establishing a regular reporting system through health facilities or special studies will ensure ongoing monitoring. Ideally reporting on ADRs related to ACTs will be integrated into a larger system for reporting on such events for all medicines. Indicator 16 relates to reporting of ADRs associated with ACTs.

16. Percentage of health facilities that have procedures in place to report ADRs associated with ACTs

Definition, rationale, and interpretation	Measures the proportion of facilities that have a formal system to monitor and report ADRs associated with ACTs Monitoring any adverse events associated with ACT use is important for a number of reasons. Artemisinins are relatively new; experience in their use is limited. Furthermore, although artemisinins are not currently approved for use in the first trimester of pregnancy, they will likely be given to a cohort of the pregnant population who are unaware they are pregnant. ¹⁷ As such, reporting of outcomes associated with unintentional exposure to artemisinins during the first trimester will be important.
Suggested data source	Facility reports; pharmacovigilance unit
Stakeholders to interview	Pharmacovigilance officer; health facility staff
Frequency	Annually
Type of indicator	Process
Calculation	<u>Numerator</u> : Number of health facilities that have procedures in place to report ADR <u>Denominator</u> : Total number of health facilities
Data collection form	DUS-1
Notes and caveats	

Product Quality Surveillance

To ensure that the medicines available within the health system meet appropriate quality standards, monitoring product quality is essential at all levels of the system. A comprehensive system includes ensuring quality at the time of pharmaceutical registration, during procurement, and at distribution through the public and private sectors.¹⁸ Such a system would also include

¹⁵ WHO. 2002. *The Importance of Pharmacovigilance (Safety Monitoring of Medicinal Products)*. Geneva: WHO.

¹⁶ Banoo, S., and A. Stergachis. 2007. Strengthening Pharmacovigilance Systems (MS PowerPoint presentation made at MSH Strengthening Pharmaceutical Systems launch in Arlington, VA).

¹⁷ RPM Plus Program. 2005. *Changing Malaria Treatment to Artemisinin-based Combinations: An Implementation Guide*. Arlington, VA: Management Sciences for Health.

¹⁸ RPM Plus Program. 2005. *Changing Malaria Treatment to Artemisinin-based Combinations: An Implementation Guide*. Arlington, VA: Management Sciences for Health.

mechanisms for the removal from the health system of medicines found, through product quality monitoring, to be of substandard quality. Indicators 17 and 18 address surveillance.

17. Percentage of ACT shipments received in the past 12 months that have been rejected based on quality issues (poor or substandard quality or that do not meet quality standards)

Definition, rationale, and interpretation	Measures whether or not ACT shipments are monitored for quality at the point of entry Once products are registered in the country, they must be tested for quality at the port of entry to ensure that medicines of good quality are allowed into the country and that quality presented at registration is maintained in supplies sent to the country following orders.
Suggested data source	National Drug Regulatory Authority; NMCP
Stakeholders to interview	Director of the National Drug Regulatory Authority or Quality Assurance/Quality Control Manager; NMCP quality assurance focal point
Frequency	Annually
Type of indicator	Outcome
Calculation	<u>Numerator</u> : Number of shipments rejected based on quality issues <u>Denominator</u> : Total number of shipments received
Data collection form	Central- or national-level questionnaire
Notes and caveats	Quality control testing of batch or lot samples can be conducted by a competent local quality control laboratory, or samples can be shipped to a regional WHO qualified quality control laboratory.

18. Percentage of samples of circulating ACT stocks that were tested in the past 12 months and found to be substandard

Definition, rationale, and interpretation	Measures whether antimalarial medicines are monitored for quality once they are introduced into the health system. Because the conditions under which medicines are transported, stored, and dispensed can affect their quality and thus efficacy, countries must implement a product quality surveillance (post-marketing surveillance) system to detect problems with the quality of medicines circulating in the system.
Suggested data source	National Drug Regulatory Authority; NMCP
Stakeholders to interview	Director of the National Drug Regulatory Authority or Quality Assurance/Quality Control Manager; NMCP quality assurance focal point
Frequency	Annually
Type of indicator	Outcome
Calculation	<u>Numerator</u> : Number of samples confirmed to be substandard <u>Denominator</u> : Total number of samples tested
Data collection form	Central- or national-level questionnaire
Notes and caveats	If samples have been identified, following up on the existence of procedures to remove these batches or lots from the circulating medicine supply would be interesting.

ANNEX 3. DATA COLLECTION TOOLS

- a. Central- or national-level questionnaire
- b. Other data collection forms for use in medical stores, health facilities, and private facilities or retail pharmaceutical outlets (DAS and DUS forms)

Central- or National-Level Questionnaire

Names of Interviewer: _____ Date of Interview: ___/___/___

Time of Interview: _____

Name of Facility: _____

Designation of Interviewees: (1) _____ (2) _____
(3) _____ (4) _____

1. List of ACTs found in country—

ACT Type	Registered in Country? (Yes/No)	Decision Based on Scientific Evidence? (Yes/No)

2. Is a committee or working group responsible for quantification?

- (1) Yes → How many members ? _____
→ How many have received quantification training in the
past year? _____
- (2) No

3. How many shipments of ACTs have been received completely and on time (according to the delivery schedule)? _____
(Obtain copy of delivery schedule for ACT shipments.)

Shipment Date	Complete? (Yes/No)	According to Delivery Schedule? (Yes/No)

4. When receiving ACTs, do you always check the quantity received against the receipt voucher?

(1) Yes

(2) No

If yes, have there been any discrepancies in the past year?

(1) Yes → Specify _____

(2) No

5. In the past 12 months, have any shipments of defective or substandard goods been delivered? (Check the total number of shipments.)

(1) Yes→

Specify number _____

Actions taken

How many of these shipments were rejected? _____

(2) No

6. Does the purchase order specify the minimum shelf life of the items to be procured?

(1) Yes → Specify _____

(2) No

7. In the past year, have you received any items for which the minimum shelf life equaled or exceeded the shelf life specified on the purchase order? (Check the total number of items received.)

(1) Yes→ Specify number _____

(2) No

8. How many products (i.e., ACTs from the circulation) were submitted for testing during in the past 12 months? _____

9. How many of the products submitted for testing during the past 12 months failed the test?

Central or National-Level Questionnaire. Use for indicators 1, 9,11,12,17, and 18.

DUS and DAS Forms

DUS-1. Medical Records and Facility Review Form: Uncomplicated Malaria [page 1 of 3]

Facility Code:	Data Collector Code:	Date:
Facility Type:	Location:	

- A. Does the facility have a copy of the national malaria treatment guidelines? Yes ___ No ___
If yes, from what year? _____
- B. Does the facility have IEC materials and job aids related to ACTs? Yes ___ No ___
- C. Does the facility have procedures in place to report ADRs? Yes ___ No ___
- D. Data collected from:
Medical records
Patient registry
Prenatal records
Health facility staff
Other (specify)

DUS-1. Medical Records and Facility Review Form: Pregnant Women (Prenatal) [page 3 of 3]

Facility Code:	Data Collector Code:
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Encounter Number	Col. 1	Age (Years)	Col. 2	Prescribed IPT (Yes/No)	Col. 3	Date	Col. 4	Prescriber Type	Col. 5	Medicine Name, Strength, and Dosage Form	Col. 6	Quantity Prescribed	Col. 7	Quantity Dispensed	Col. 8	Number of Units	Col. 9	Full Course Prescribed (Yes/No)	Col. 11	Full Course Dispensed (Yes/No)	Col. 12	
1		24	Yes	5/99	Nurse		10	10								1		Yes		Yes		

DUS-1. Use for indicators 3, 4, 5, 6, and 16. Data collectors should not fill the shaded columns.

DUS-2. Observation of Health Worker Data Form [page 1 of 2]

Facility Code:	Data Collector Code:	Facility Type:	
Location:	Date:	Encounter Number:	
Sex (M/F):	Pregnant (Y/N):	Age:	Diagnosis:

A. Write down exactly any questions that the health worker asks the patient or caregiver about the illness or symptoms of illness.

B. Write down exactly what the health worker says about what to do if the illness does not get better.

DUS-2. Observation of Health Worker Data Form [page 2 of 2]

C. For each medicine that the health worker or prescriber gives or prescribes, write down the following information:

Medicine Name, Strength, and Dosage Form	Dosage Quantity	Frequency	Duration of Treatment (Days)	Administration	Full Course Prescribed (Yes, No, N/Av)
Col. 1	Col. 2	Col. 3	Col. 4	Col. 5	Col. 6
Fansidar	3 tablets	once	1 day	with food	yes
1. Did the health worker explain to the patient or caregiver how to take or give the medication? Yes ___ No ___					
2. Was the treatment consistent with STGs? Yes ___ No ___					
3. Did the health worker ask one or more clinical questions to determine the severity of malaria? (optional) Yes ___ No ___					
4. Did the health worker tell the patient or caregiver about any signs of progressive illness and recommend a referral visit if the signs appear? (optional) Yes ___ No ___					
5. Was the patient treated with an ineffective antimalarial? Yes ___ No ___					

DUS-2. Use with indicators 5 and 8.

DUS-3. Exit Poll Interview Form [page 1 of 1]

Facility Code:	Data Collector Code:	Facility Type:	
Location:	Encounter Number:	Interview Number:	
Sex (M/F):	Pregnant (Y/N):	Age:	Date:

Ask the patient or caregiver: "What was the chief complaint or the reason for the consultation (i.e., the health problem)?"
 Ask the patient or caregiver: "What medicines were prescribed and how are you going to take them or give them to the patient?"

Name of Medicine	Dosage Quantity	Frequency	Duration of Treatment (Days)	Administration	Did the Patient or Caregiver Receive the Medicine? (Yes/No)	Quantity Dispensed
Col. 1	Col. 2	Col. 3	Col. 4	Col. 5	Col. 6	Col. 7
Fansidar	3 tablets	once	1 day	with food	yes	3 tablets
Row 1. Total number of medicines prescribed _____						
Row 2. Can patient or caregiver correctly describe how to take or give prescribed medication(s)? Yes ___ No ___						
Row 3. Total number of medicines dispensed _____						
Row 4. Did the prescription cover a full course of treatment? Yes ___ No ___						
Row 5. Did the quantity dispensed cover a full course of treatment? Yes ___ No ___						

DUS-3. Use with indicators 5 and 7.

DUS-4. Simulated Purchase Data Form for Uncomplicated Malaria in Private Pharmacies [page 1 of 1]

Facility Name:	Date:
Location:	

For all medicines recommended for purchase by the medicine seller, write the following information.

Medicine Name, Strength, and Dosage Form	Dosage Quantity	Frequency	Duration of Treatment (Days)	Administration	Price	Full Course Prescribed (Y/N/NAv)
Col. 1	Col. 2	Col. 3	Col. 4	Col. 5	Col. 6	Col. 7
Fansidar	2 tablets	once	1 day	with food	12	Yes
Row 1. Did the dispenser provide some information on how to take the medicines? Yes ___ No ___						
Row 2. Did the dispenser prescribe medicines in line with STGs? Yes ___ No ___						
Row 3. Total cost of prescribed treatment (Total of column 6)---						
Row 4. STG cost---						
Row 5. Percentage of STG cost---						

DUS-4. Use with indicators 5 and 8.

DAS-2. Inventory Data Form: Health Facility [page 1 of 2]

Facility Code:	Data Collector Code:	Date:
Facility Type:	Location:	

Existing inventory control systems:

Computerized _____
 Manual ledger _____
 Tally, bin, or stock record cards _____
 Other (specify) _____

Data collected from:

Computerized _____
 Manual ledger _____
 Tally, bin, or stock record cards _____
 Other (specify) _____

Is a system in place to track and report ACT consumption? Yes _____ No _____

Note:

- **Data collectors should not fill out the shaded rows or columns.**
- ALL blanks should be filled in on this data form.
- Enter "N/Av" if data for a particular item are not available from the records or from the health care workers.

