Assessment of the Use of Antimalarial Medicines in Public and Private Sectors of Kenya: Research Findings for Evidence-Based Strategy Development, April 2006

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Strategic Objective 5

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ACRONYMS

ACT	artemisinin-based combination therapy
AL	artemether-lumefantrine
AQ	amodiaquine
DOMC	Division of Malaria Control
DUS	drug use study
INRUD	International Network for Rational Use of Drugs
IPT	intermittent preventive treatment
KEDL	Kenya Essential Drugs List
MoH	Ministry of Health
MSH	Management Sciences for Health
PMM	Pharmaceutical Management for Malaria
PTC	Pharmacy and Therapeutics Committee
RPM Plus	Rational Pharmaceutical Management Plus Program
SP	sulfadoxine/pyrimethamine
STG	standard treatment guideline
USAID	U.S. Agency for International Development
WHO	World Health Organization

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EXECUTIVE SUMMARY

Widespread resistance to antimalarial monotherapies in Kenya prompted a recent change in the national malaria treatment policy in favor of a more effective artemisinin-based combination therapy (ACT), artemether-lumefantrine (AL). In April 2005, Kenya adopted the policy change in malaria treatment policy, and the distribution of AL under the new policy began in June 2006 and is currently ongoing. Implementation of the new treatment policy by health workers is scheduled to begin following a launch of the new policy on September 25, 2006. Until then, health facilities are still using sulfadoxine/pyrimethamine (SP) and amodiaquine (AQ) for first- and second-line treatment of uncomplicated malaria, respectively.

The Kenya Division of Malaria Control (DOMC), Ministry of Health (MoH), recognizes that irrational diagnosing, prescribing, and dispensing by health workers and nonadherence by patients and caregivers will lead to development of resistance, treatment failure, adverse drug reactions, and waste of financial resources. In comparison to previously used antimalarial monotherapies, the brand of AL currently being distributed for use in the public sector, Coartem®, has peculiarities that need to be considered when it is used. These peculiarities include the fact that Coartem is expensive, it has a complicated dosage regimen (presented in different packages of 6, 12, 18, and 24 tablets for treatment by patient weight band), and health workers lack experience with its use.

To ensure the effectiveness of the new policy, the DOMC has requested technical assistance from the Rational Pharmaceutical Management (RPM) Plus Program of Management Sciences for Health (MSH) to design and promote the implementation of strategies for the rational use of Coartem among health workers and their clients. In response to the DOMC's request to RPM Plus, a Rational Use of Antimalarial Medicines Consultative Workshop is planned for December 2006 with the DOMC. The workshop will target approximately 40 participants comprising major stakeholders from the public and private health sectors involved in formulating and implementing policies on the diagnosing, prescribing, and dispensing of antimalarial medicines. To guide the planning and content of this meeting, RPM Plus and the DOMC undertook this rapid assessment of the aspects of the pharmaceutical management system in the public and private sectors that are crucial to ensure the proper use of the new recommended combination therapy. The U.S. Agency for International Development (USAID) provided funding.

Methodology for the rapid assessment was based on the *Pharmaceutical Management for Malaria (PMM) Manual*'s drug use study (DUS). The PMM is an indicator-based assessment tool developed by the Rational Pharmaceutical Management project in collaboration with USAID. The purpose of conducting the DUS was to review prescribing and dispensing practices for malaria and to assess their clinical implications. The drug use information obtained is expected to guide prescriber involvement in implementing the new malaria treatment policy and to target specific behaviors through training, subsequent monitoring, and supervisory activities as well as through behavior change communication targeting the general public. The DUS used both retrospective and prospective methods of assessment.

Four districts were selected for the purposes of this assessment: Kwale, Makueni, Bondo, and Kisii Central. A total of 80 public health and private sector facilities, including retail pharmaceutical outlets, were sampled, 10 from each of the four selected districts. The facilities were selected either randomly, using a random number generator, or purposively.

The rapid assessment highlighted some positive findings as well as challenges in the use of antimalarial medicines in the facilities surveyed, as follows—

- Overall, very few facilities had at least one copy of the national treatment guidelines for malaria available. The low availability of guidelines in health facilities means that the majority of health workers do not have ready access to a reference source that supports appropriate prescribing.

- With no reference source readily available, health workers did not prescribe an appropriate antimalarial to more than half of patients and caregivers of patients with uncomplicated malaria. Health workers cannot adhere to malaria treatment guidelines if they do not know what they are and cannot refer to them when a diagnosis of malaria is made.

- Approximately three-quarters of prescriptions written for patients and caregivers of patients antimalarial were for quantities sufficient for a full course of treatment. However, SP and AQ, the recommended first- and second-line treatments for uncomplicated malaria, have a very simple dosage regimen (one dose each of three tablets) compared with the future recommended treatment, artemether-lumefantrine.

- A high level (over 90 percent) of dispensing by health facilities of prescriptions presented indicates the presence among health workers of good dispensing practices as well as the ready availability in health facilities of recommended medicines.

- Over 80 percent of patients and caregivers of patients could describe correctly how to take or give the prescribed antimalarial medication. However, the observation of health workers showed that less than half of them in Ministry of Health (MoH) facilities provided some information to the patients or caregivers on how to take or give the recommended medicines. This finding demonstrates that the long-term use of SP and AQ, their simple dosage regimen, and general public education have enabled patients and caregivers to learn how to administer the recommended medications, rather than instructions from health workers.

- An average of 80 percent of pregnant women attending health facilities received intermittent preventive treatment (IPT) to prevent malaria. All the women who received IPT received the nationally recommended medicine, SP.

The indicators presented in this report should be viewed as the first step in a process of investigation of the problems discussed in the report. The rapid nature of this assessment did not allow in-depth determination of the challenges identified. The findings are simply meant to help the Division of Malaria Control recognize the challenges, where they exist. It is recommended

that the DOMC carry out further investigation using more qualitative methods during routine monitoring and supervision to determine reasons for the challenges identified. Further investigation of the challenges will help determine why irrational prescribing, inaccurate dispensing, inappropriate patient medication counseling, and patient and caregiver nonadherence to recommended antimalarial treatments occur and which factors contribute to it.

As a next step and to improve the implementation of the new ACT policy, the findings highlighted in this report will be used as an evidence base for discussion by key Roll Back Malaria and pharmaceutical sector stakeholders in the planned Rational Use of Antimalarial Medicines Consultative Workshop. The goal of the workshop will be to design, promote, and implement realistic strategies for improving the rational use of antimalarial medicines. The design and subsequent promotion of interventions should take into account already existing interventions, and discussions should select and target interventions where the greatest need for improvement and the greatest likelihood of achieving impact exist.

INTRODUCTION

Background

Kenya's Malaria Treatment Policy Change

Widespread resistance to sulfadoxine/pyrimethamine and amodiaquine in Kenya prompted a recent change in the national malaria treatment policy in favor of a more effective artemisinin-based combination therapy, artemether-lumefantrine. Kenya adopted the treatment policy change in April 2005, and the distribution of AL under the new policy began in June 2006 and is currently ongoing. Following a launch of the new policy on September 25, 2006, health workers recently began implementation of the new treatment policy. Until then, all public health facilities were still using SP and AQ for first- and second-line treatment of uncomplicated malaria, respectively.

In preparation for policy implementation, the Division of Malaria Control of the Ministry of Health updated the national malaria treatment guidelines to guide health workers in managing malaria cases using the new ACT. Effective case management of malaria requires that effective and appropriate antimalarials are not only available but are also used appropriately in the correct formulations and quantities and according to an appropriate regimen.

Coartem, the selected first-line antimalarial treatment, is a fixed-dose ACT and, as its name suggests, combines artemether—a derivative of artemisinin extracted from the Chinese sweet wormwood plant *Artemisia annua*—with lumefantrine. Using both medicines in a single-dose formulation combines the benefits of artemether's fast onset of action (parasite clearance) with lumefantrine's long duration of action and high cure rate. Thus, the carefully selected AL is a promising and efficacious ACT expected to play a key role in reducing the high morbidity and mortality of groups vulnerable to malaria in Kenya.

To ensure the availability of AL for case management within public sector health facilities, the Global Fund to Fight AIDS, Tuberculosis and Malaria has provided a grant to Kenya to procure Coartem, the only prequalified World Health Organization (WHO) fixed-dose brand of AL, under a special global agreement between the WHO and the supplier (Novartis). Since the arrival of procured consignments of subsidized Coartem in country, the Kenya Medical Supplies Agency[1] and the Mission for Essential Drugs and Supplies[2] have been distributing quantities to MoH and mission sector health facilities, where the product is to be supplied to patients free of charge or not for profit. The use of Coartem for case management by health workers has been fully functional since October 2006.

[1] The Kenya Medical Supplies Agency has a key mandate of procuring, warehousing, and distributing health commodities to Kenya's public sector.

[2] The Mission for Essential Drugs and Supplies has a mandate of ensuring a reliable supply of good-quality essential medicines and supplies at affordable prices to its clientele: church health facilities, other religious organizations, some nongovernmental organizations, relief agencies, and community-based initiatives.

Compared with previously used antimalarial monotherapies, Coartem has peculiarities that have been considered by the Government of Kenya during its quantification, procurement, and storage and that will be considered with use. These peculiarities include the fact that Coartem is expensive, has a complicated presentation (presented in different packages[3] of 6, 12, 18, and 24 tablets for treatment by patient weight band), has a 14-month lead time for production,[4] and has a short shelf life; and health workers lack experience with its use.

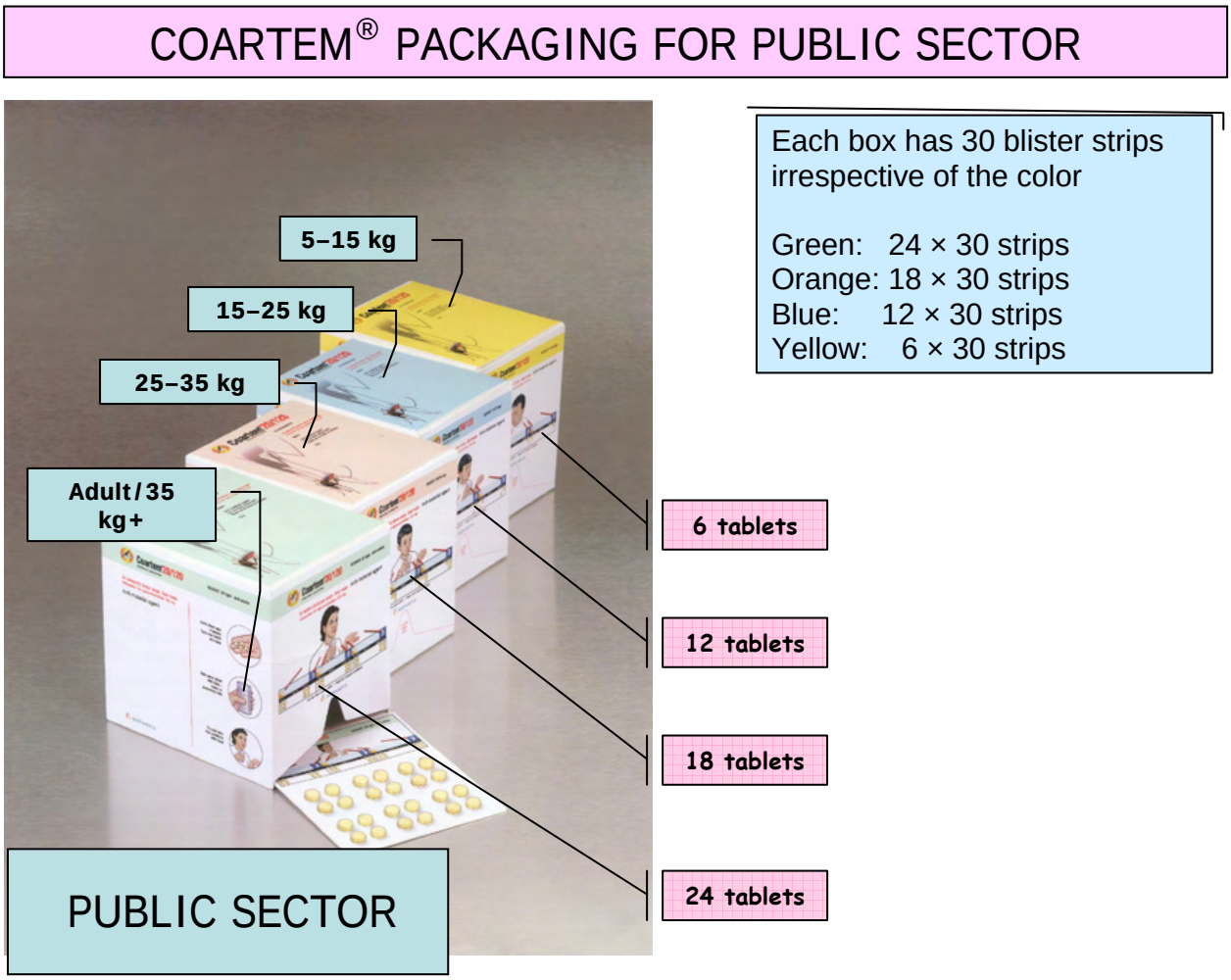

Figure 1. Artemether-lumefantrine (Coartem) public sector packaging

The Kenya DOMC recognizes that irrational diagnosing, prescribing, and dispensing by health workers and nonadherence by patients and caregivers will lead to development of resistance, treatment failure, adverse drug reactions, and waste of financial resources. The DOMC has requested technical assistance from the RPM Plus Program of MSH to design and promote the

[3] The primary (strip) and secondary packaging are color coded to facilitate distinguishing among the dose categories.
[4] Lead time for production includes planting, harvesting, extraction of artemisinin, manufacturing tablets, packaging, and finally, shipment of the product.

implementation of strategies for the rational use of Coartem among health workers and clients to ensure the effectiveness of the new policy.

Recommended strategies and interventions will build on existing rational use of medicines strategies within the National Drug Policy of Kenya.

Rational Use of Medicines in Kenya

In its National Drug Policy of July 1994, the Government of Kenya outlined the rational use of medicines as a specific objective and is facilitating this objective through sound prescribing, good dispensing practices, and appropriate use. In May 2006, the MoH revised its National Drug Policy to include new strategies; however, challenges that continue to hinder the rational use of medicines in Kenya include—

- Lack of medicines in health facilities
- Staff shortages
- Lack of continuing medical education
- Failure of timely updates to standard treatment guidelines (STGs) and Kenya Essential Drugs List (KEDL)
- Insufficient distribution of national STGs and EDLs to health facilities
- Lack of regard for national STGs and EDLs in some private establishments caused by monetary incentives from drug manufacturers and their agents
- General apathy of health care workers

The following are key pillars of the strategy for rational use of medicines in Kenya.

The Essential Drugs List

The Kenya Essential Drugs List is updated regularly (current version is 2003). Updates of the KEDL are done by the National Pharmacy and Therapeutics Committee, which consists of 18 members who are stakeholders in pharmaceutical management.

The criteria for including medicines in the KEDL are—

- Quality, safety, and cost
- Intended level of care at which medicines will be use
- Epidemiological profile

Use of Standard Treatment Guidelines

Standard treatment guidelines for health facilities in Kenya are regularly updated[5] and made available in Government of Kenya health facilities. Other health facilities (private, nongovernmental, and mission) are encouraged to use the same guidelines. Use of the guidelines is encouraged through information campaigns and preservice and in-service training. In addition, rural health facilities use the *Handbook for Rural Health Workers* and various charts.

The KEDL and STGs are harmonized to ensure that medicines in the KEDL are consistent with disease conditions in the treatment guidelines.

Generic Prescribing

The use of generic names (international nonproprietary name, or INN) is being encouraged across the entire pharmaceutical management system. The use of generic names is also being mainstreamed in preservice institutes (e.g., pharmacy and medical training colleges).

Education and Training

All pharmacology and therapeutic training in medical, pharmacy, dental, nursing, and paramedical schools is based on the essential medicines concept. Professional bodies are mandated to enforce continuous medical education as a prerequisite for license renewal.

Pharmacy and Therapeutics Committees

Each health institution is being encouraged to set up a Pharmacy and Therapeutics Committee (PTC). Each PTC is expected to be chaired by the institution's Medical Superintendent and convened by a pharmacist within the institution. Other members of the PTC are clinicians, nurses, and public health officers. PTC members oversee medicine selection and formulary management in their institutions.

Medicine Information

A medicine information center has been established at the Pharmacy and Poisons Board in Kenya. The center is headed by a clinical pharmacist and works to ensure that all locally manufactured and imported products have adequate information on indications, pharmacology, side effects, toxicology, precautions, and contraindications.

Advertising and Promotion of Medicines

The medicine information center at the Pharmacy and Poisons Board enforces regulation of product promotion. This regulation ensures that product promotion and advertising are ethical, factual, educational, and balanced in approach. The regulatory and legal framework is enforceable under cap. 244 of the laws of Kenya.

[5] The chief pharmacist institutes a committee of clinicians, nurses, pharmacists, and clinical officers at the time of updating; the committee is headed by the deputy director of medical services.

Kenya was recently appointed to the International Board of the International Network for Rational Use of Drugs (INRUD), which underscores the country's commitment to institutionalizing rational use of medicines

Rational Use of Coartem

Working within the overall strategies for rational use of medicines in Kenya to ensure the rational use of Coartem, the DOMC on its part has ensured that the following criteria for the rational use of Coartem are met—

- Appropriate medicine: The process of selecting AL as first-line treatment for uncomplicated malaria ensured that it was the most appropriate medicine (considering efficacy, safety, suitability and safety for the patient, and cost).

- Appropriate dosage, administration, and duration of treatment: Coartem is prepackaged in a way that allows for dispensing of the appropriate dosage, administration, and duration of treatment.

The remaining criteria for rational use of Coartem, namely—

- appropriate indication, reason to prescribe is based on sound medical considerations;

- appropriate patient, that is, no contraindications exist and the likelihood of adverse reactions is minimal;

- correct dispensing, including appropriate information to patients about the prescribed medicines;

are largely dependent on the health worker. Although the DOMC has set the stage for rational prescribing and dispensing behaviors by updating the national malaria treatment guidelines and providing training on them, to conform with these criteria, health workers should follow a standard process.

Justification for the Rapid Assessment

As a first step in designing and implementing strategies for the rational use of Coartem, a rapid assessment of the prescribing and dispensing practices of health workers in public and private sector health facilities and retail pharmaceutical outlets was undertaken using funds from the United States Agency for International Development (USAID). Following the assessment, a Rational Use of Antimalarial Medicines Consultative Workshop is planned for December 2006 with the Division of Malaria Control. The workshop will target approximately 40 participants comprising major stakeholders from the public and private health sector involved in formulating and implementing policies on the diagnosing, prescribing, and dispensing of antimalarial medicines. Findings of the rapid assessment are meant to guide the planning and content of the planned consultative workshop.

METHODOLOGY

Assessment Methodology

Methodology for the rapid assessment was based on the *Pharmaceutical Management for Malaria Manual*, an indicator-based assessment tool developed by the RPM project in collaboration with USAID. The *PMM Manual* is designed to guide the overall review of availability and patterns of use of medicines for malaria treatment in public health facilities, private facilities, and pharmaceutical retail outlets, including pharmacies. This particular assessment was built on the Drug Use Study (DUS) component within the *PMM Manual*.

Drug Use Study

The purpose of conducting the DUS was to review prescribing and dispensing practices for malaria and to assess their clinical implications. The drug use information obtained is expected to guide the involvement of prescribers in implementing the new malaria treatment policy and to target specific behaviors through training, subsequent monitoring, and supervisory activities as well as through behavior change communication targeting the general public.

The DUS used both retrospective and prospective methods of assessment. For the retrospective component of the study, the data collection technique used was the review of medical records in MoH, mission, and formal private sector facilities. The prospective component used techniques of direct observation and exit poll interviews in MoH, mission, and formal private sector facilities and simulated purchases in pharmaceutical retail outlets.

Drug Use Study Indicators

Seven PMM indicators were used to assess the use of antimalarial medicines for the treatment of malaria in the public and private sectors of Kenya. The DUS indicators, listed below, focused on current medicine use practices for treating malaria in the health system.

1. Percentage of MoH, mission, and private sector health facilities visited that had a copy of the official treatment guidelines for malaria

2. Percentage of encounters with patients diagnosed with uncomplicated malaria in which they were prescribed an antimalarial consistent with treatment guidelines

3. Percentage of encounters with patients diagnosed with uncomplicated malaria in which they were prescribed quantities of appropriate antimalarials sufficient to complete a full course of treatment

4. Percentage of prescribed antimalarial medicines actually dispensed by health facilities

5. Percentage of patients/caregivers who could correctly describe how to take/give the prescribed antimalarial medication

6. Percentage of health workers and retail pharmaceutical outlets that provided [some] information to patients/caregivers on how to take/give the recommended medicine(s)

7. Percentage of encounters with pregnant women living in malaria-endemic areas who were prescribed an appropriate antimalarial for intermittent preventive treatment (IPT) at prenatal clinics

To conduct the DUS, data were collected at the district and health facility levels. In addition, a literature search and review of relevant background documents were conducted.

Preparation of Data Collection Tools

Data collection tools were adapted from RPM Plus's *PMM Manual* for this assessment. The tools included five forms, as indicated in Table 1. (Copies of the forms are included in Annex 2.)

Table 1. Data Collection Tools for the Rapid Assessment

Form Name	Code	Personnel Interviewed	Number of Forms Used per Facility
Medical Records Review Form—Uncomplicated Malaria	DUS-1A	Medical Records Officer/Nurse	30
Medical Records Review Form—Pregnant Women	DUS-1B	Medical Records Officer/Nurse	10
Observation of Health Worker Form	DUS-2	Facility Supervisor	10
Patient/Caregiver Exit Interview Form	DUS-3	Facility Supervisor	10
Simulated Purchase Form	DUS-4	In-charge/pharmacist at outlet	1 per retail pharmaceutical outlet

Sampling

Selection of Districts

Four districts were purposively selected for the purposes of this assessment: Kwale, Makueni, Bondo, and Kisii Central. These districts are DOMC districts and are ecologically diverse[6] districts for malaria.

Selection of the Public Health Facilities Sample

A DOMC database of all MoH and mission health facilities in Kenya provided the sampling framework to select public health facilities within sampled districts. A total of 40 public health facilities were sampled, 10 from each of the four selected districts. The facilities were selected either randomly using a random number generator or purposively. The rationale for selecting a

[6] The level of endemicity of malaria in Kenya varies from region to region and the country has a huge diversity in population risk to malaria, largely driven by climate and temperature (including the effects of altitude).

minimum sample size of 40 health facilities was based on previous studies and using methodologies extrapolated from WHO Expanded Programme on Immunization and INRUD studies, and the study design factors.

Within each district, one Provincial General Hospital or MoH district hospital and one mission hospital were selected to be visited. In addition, four health centers were randomly selected. For each of these four health centers, one dispensary that was geographically close was selected. For each district, backup facilities[7] were also selected through similar processes before the start of and during fieldwork.

Selection of the Private Facilities and Pharmaceutical Retail Outlet Sample

For the purposes of the assessment, private health facilities referred to private hospitals and clinics and retail pharmaceutical outlets such as pharmacies and other outlets.

A sample of 40 facilities, 10 from each of the four districts, was selected. From a sample frame of private facilities, a sample of two private hospitals or clinics and eight geographically close pharmacies and retail pharmaceutical outlets were randomly selected. These retail outlets were used for the simulated purchase scenario. For each district, backup facilities were selected as was done for the public sector facility selection.

To ensure confidentiality, each facility was assigned a code.

Recruitment and Training of Data Collectors

RPM Plus, in conjunction with DOMC, selected and trained data collectors for fieldwork. They agreed that 16 data collectors would be needed and that the most effective data collectors would be pharmacists and pharmacy technologists. Data collectors were drawn from the national, provincial, and district levels of Kenya's public health system.

Training was conducted for the data collectors over a three-day period in Nairobi. The training gave the data collectors a brief background on the malaria situation in Kenya and the purpose of the antimalarial medicine use assessment. During the training, the data collection tools and data collection techniques relevant to the assessment were reviewed. Discussions were held on the anticipated challenges that would be faced in the field.

The list of the facilities to be sampled and their locations was shared with the data collectors, and two teams were constituted. Each team was headed by a qualified public sector pharmacist, and each team was assigned to two districts for fieldwork. The list of teams, schedule of work, and sequence of fieldwork was discussed and finalized. The training session provided an excellent opportunity to build the teams on the basis of qualification and aptitude of the data collectors. On the final day of training, a field test was carried out in Machakos District in one district hospital, one dispensary, and one retail pharmaceutical outlet. The field test exposed data

[7] Backup facilities were selected in the event that one of the MoH hospitals, rural health facilities, or mission health facilities was closed or unable to provide the required data.

collectors to the practicalities of administering the tools and provided a good review of data collection techniques, such as record reviews, exit poll interviews, and direct observation, as well as insight into what to expect during the actual assessment. Feedback from this field test was used to adapt data collection tools.

Logistics and administrative matters were addressed before the teams traveled into the field.

Data Collection

Data collection was conducted over a two-week period, April 10–21, 2006, in Makueni, Kwale, Bondo, and Kisii-Central districts. Each of the two teams consisted of eight data collectors (see Annex 1). Sites sampled during the assessment are shown in Table 2.

Table 2. Health Facilities, including Number of Pharmaceutical Retail Outlets

District	Facility Type	Facility Name
Kwale	District Hospital	Msambweni District Hospital
	Health Centre	Samburu Kwale Health Centre
		Shimba Hills Health Centre
		Tiwi Rural Health and Rural Training Centre
		Kikoneni Health Centre
	Dispensary	Muhaka Dispensary
		Mamba Dispensary
		Waa Dispensary
		Kwale Dispensary
	Mission Hospital	Banga Outreach Clinic
	Private Hospital	Nafuu Medical Clinic
		Ukunda Health Clinic
	Retail Pharmaceutical Outlet	8 retail pharmaceutical outlets
Makueni	District Hospital	Makueni District Hospital
	Health Centre	Tawa RHDC Health Centre
		Kikumini Health Centre
		Mavindini Health Centre
		Kalawa Health Centre
	Dispensary	Kitala Dispensary
		Kivaani Dispensary
		Nziu Dispensary
		Ukia Dispensary
	Mission Hospital	Kikoko Mission Hospital
	Private Hospital	Memorial Clinic
		X-ray clinic
	Retail Pharmaceutical Outlet	8 retail pharmaceutical outlets

Bondo	District Hospital	Bondo District Hospital
	Health Centre	Abidha Health Center
		Pap Kodero Health Centre
		Madiany Health Centre
		Manyuanda Bondo Health Centre
	Dispensary	Usigu Dispensary
		Ndori Dispensary
		Masala Dispensary
		Gobei Dispensary
	Mission	St. Elizabeth Lwak Mission Hospital
	Private Hospital	Uhanya Medical Clinic
		God Heals Clinic
	Retail Pharmaceutical Outlet	8 retail pharmaceutical outlets
Kisii Central	District Hospital	Kisii District Hospital
	Health Centre	Riana Health Centre
		Oresim Health Centre
		Kiogoro Health Centre
		Ibeno Health Centre
	Dispensary	Taracha Dispensary
		Matongo Dispensary
		Iyabe Dispensary
		Daganga Dispensary
	Mission Hospital	Itierio M & NH
	Private Hospital	Bosongo Medical Centre
		Hema Hospital
	Retail Pharmaceutical Outlet	8 retail pharmaceutical outlets

The following data collection techniques were used at the facilities visited in districts sampled.

Patient Medical Records Review

These reviews served as the primary source of retrospective data on prescribing practices used to treat malaria in public sector facilities visited. To achieve these reviews, the patient encounter samples were selected in each of the public health facilities and formal private health facilities (hospitals and clinics) as follows.

Selection of the Patient Encounter Sample (Uncomplicated Malaria)

For uncomplicated malaria, 1,440 patient encounter records were reviewed. This number was achieved by randomly selecting 30 medical records for malaria in each of the 40 public health facilities and the 8 private hospitals or clinics visited, using the interval approach. Examples of patient encounter records included medical records and patient-held record cards. The rationale for selecting a minimum sample size of 30 malaria patient encounters per facility is that experience has shown that the results of collecting larger samples are generally not more useful for identifying the main problems and therefore do not justify the increased time, cost, and effort.

Selection of Patient Encounter Samples for IPT

Ten prenatal records for pregnant women per health facility were reviewed to determine the provision of IPT for malaria by health workers. The interval approach of random sampling was used for selection of patient records.

Direct Observation

This technique required that data collectors directly observe the behavior of health workers for the purpose of describing particular prescribing practices. During this nonparticipatory observation, the data collector recorded information as inconspicuously as possible, using the direct observation tool.

Selection of Patient Encounter Samples for Direct Observation

Ten cases were selected out of the selected uncomplicated malaria patient encounters. Again, the interval approach of random sampling was used.

Exit Poll Interviews

Malaria patients and caregivers of children and adults who were sick with malaria were the target audience for the exit poll interviews. This data collection technique was used to determine how well each patient or caregiver understood the instructions given by the health worker or medicine dispenser about the medicine prescribed and about follow-up care in case of worsening conditions, as well as whether the patient or caregiver had obtained the prescribed medication.

Selection of Exit Poll Interview Sample

Ten patients or caregivers of patients were interviewed at each public health facility and retail pharmaceutical outlet. In health facilities, patients interviewed were the same patients whose consultation process was directly observed. The exit poll interview and direct observation of consultation were handled by different data collectors.

Simulated Purchases in Retail Outlets

To collect data using this technique, data collectors posed as ordinary customers and purchased treatment for malaria from retail pharmaceutical outlets. One simulated purchase was made per selected retail outlet.

Challenges in Data Collection

The data collectors faced some major challenges during the data collection period.

Time Constraints and Poor Patient Turnout

Patients in the different districts visited the health centers at different times depending on their daily activities. In some of the smaller facilities, achieving the required patient encounter number for direct observation and exit poll interviews was difficult. For example, in Kwale District, the patients generally visited the facilities in the morning before the heat became unbearable, while in Kisii patient turnout was affected by rain as well as farming activities. This nonavailability of patients required that data collectors spend longer periods per facility.

This challenge was overcome by splitting the teams further and carefully planning schedules in advance.

Poor Record-Keeping

In many facilities visited during the assessment, data collectors faced challenges related to patient records. The major challenged faced was that patient records are in patient booklets that are kept by the patient. Patients carried their patient booklet to and used it in all the facilities the patient had ever visited. Patients often lose these booklets or forget to bring them on subsequent visits. Therefore, most of the patients were carrying very recent records, not very useful for the retrospective review aspect of the assessment. Moreover, if patients were not present or forgot to bring the booklet, the data collector had no access to patient records.

Where a register was available, often the treatment column was missing. The outpatient register is not standardized for all facilities.

A low availability of prenatal care records was noted in some mission and private health facilities because prenatal care services are not offered in many. In many instances, prenatal care registers did not show details of IPT administration, either because the column was not filled in or it was not there at all.

Some registers record just the name of the medicine used for treatment under the treatment column, but dosage forms and dosages are not indicated. Teams had to find the missing information from facility dispensers.

Prenatal care records had only ticks/checks and not specific dates indicated against IPT administration, posing difficulty for determining at what gestation SP was given. The last menstrual period of pregnant women was also not indicated on the prenatal care cards.

Language Barrier

In several facilities, patients selected for direct observation used their local language. Although data collectors familiar with the language in particular districts were sent to those districts, full comprehension of some of the discussions during consultation was still a challenge. Because of the difficulty in observing patient encounters in small facilities, data collectors (observers) in some instances had to request the prescriber to interpret information provided to the patient.

Hostile Climates and Terrain

Some facilities visited had very difficult terrains to maneuver, which increased travel time and limited the length of time available for data collection. In Kisii District, for example, the roads became literally impassable when it rained.

Uncooperative Staff

In a few facilities, the team was unable to collect data because of lack of cooperation by the staff. In instances where staff were totally uncooperative, a backup facility was selected to replace the original facility.

Data Collation and Management

Data were edited and entered into a Microsoft Excel spreadsheet over a two-week period at the MSH regional office in Nairobi, Kenya. Data analysis was done using Excel.

FINDINGS OF THE ASSESSMENT, ANALYSIS, AND INTERPRETATION

Indicator 1. Percentage of MoH, mission, and private sector health facilities visited that had a copy of the official treatment guidelines for malaria

Description and Use of the Indicator

This indicator is used to measure the level of provider access to information that promotes effective care and management of malaria based on treatment guidelines adopted by the MoH of the country involved. Theoretically, all, or 100 percent, of facilities within all health sectors should have an official copy of the treatment guidelines for malaria. Because at the time of this assessment, the latest version of Kenya's malaria treatment guidelines—although developed—had not been disseminated, this indicator measured the presence of the previous version of treatment guidelines in health facilities. Although the presence of guidelines does not mean that staff use them, their presence does provide a reference source that supports appropriate prescribing.

Methodology

Data for this indicator were collected by a survey of 48 health facilities. At each site, staff were asked to produce a copy of the malaria treatment guidelines.

Results

Overall, very few facilities had at least one copy of the national treatment guidelines for malaria available. As Table 3 indicates, Makueni District had the largest number of facilities where treatment guidelines were available.

Table 3. Number of Health Facilities with at Least One Copy of the National Treatment Guidelines for Malaria

Facility Type	Total Number of Facilities Surveyed	Makueni	Kwale	Bondo	Kisii
District Hospital	4	1	0	0	0
Mission Hospital	4	1	0	1	0
Health Center	16	3	1	1	1
Dispensary	16	1	0	1	1
Private Clinic	8	0	0	0	0
Total	**48**	**5**	**1**	**3**	**2**

Discussion

Copies of the national treatment guidelines might not be present for a few reasons. They could either not have been given to the facility because of inadequate quantities or inadequate dissemination, or they may have been lost over the years and never been replaced. In the absence of easily accessible guidelines, practicing prescribers can be assumed to be aware of the official guidelines only through training or other forms of communication, such as informal discussion with other prescribers.

The findings that such a low percentage of facilities have the guidelines are not encouraging and suggest that the DOMC must work hard to print the required number of copies of the new guidelines and disseminate them efficiently. Currently, 1 million copies of the guidelines have been printed and are being disseminated to health workers within public health facilities in Kenya. This number, if properly disseminated, is adequate to cover health workers currently at posts in MoH, mission, and private health facilities.

Indicator 2. Percentage of encounters with patients diagnosed with uncomplicated malaria in which they were prescribed an antimalarial consistent with treatment guidelines

Description and Use of the Indicator

Following the national recommended guidelines for treating uncomplicated malaria is important to treat the patient in a timely and effective manner, contain treatment costs, and reduce the risk of contributing to the development of drug resistance. Again, because at the time of this assessment, the malaria treatment policy that recommended the use of SP for first-line treatment of uncomplicated malaria was in use, the assessment measured the treatments prescribed in accordance with the outgoing policy.

This indicator measures the adherence with national guidelines for treating uncomplicated malaria. High percentages identify a positive behavior that should be reinforced or encouraged. Low percentages identify the need for improvement.

Methodology

Data for this indicator were collected through a survey of 48 health facilities (40 public or mission and 8 private) as well as 32 retail pharmaceutical outlets. A minimum sample size of 30 malaria records and 10 observations per health facility (except in one private facility) was used to determine the number of patients with uncomplicated malaria who were prescribed appropriate antimalarials. In addition, 32 simulated purchases were conducted in retail pharmaceutical outlets to determine the appropriateness of prescribed treatment.

Results

For all health facilities surveyed, data for a sample of 1,892 patient encounters showed that an average of 46.9 percent received an appropriate antimalarial for the treatment of uncomplicated malaria. For all private pharmaceutical outlets surveyed, data for a sample of 32 simulated purchases showed that an average of 59.4 percent received appropriate antimalarials for the treatment of uncomplicated malaria.

Table 4. Percentage of Encounters Diagnosed as Uncomplicated Malaria and Prescribed Antimalarials Consistent with the National Treatment Guidelines for Malaria

Facility Type	Total Number of Facilities/Outlets Surveyed	Total Number of Encounters/ Simulated Purchases per Facility/ Outlet	Makueni	Kwale	Bondo	Kisii
District Hospital	4	162	61%	73%	60%	45%
Mission Hospital	4	129	26%	1%	44%	47%
Health Center	16	629	68%	66%	60%	36%
Dispensary	16	749	70%	85%	44%	65%
Private Clinic	8	223	41%	44%	1.6%	1.5%
Private Pharmaceutical Outlet	32	32	62.5%	75%	50%	50%
Overall	**80**	**1,924**	**54.8%**	**57.3%**	**43.3%**	**40.8%**

Discussion

Overall, the number of prescribers following the treatment guidelines is relatively low. This finding highlights the need for educating prescribers in both public and private sector facilities and pharmaceutical retail outlets on the need to adhere to recommended treatments in national guidelines. Poor adherence to the guidelines, in this instance, might result from prescriber experience with decreasing efficacy of antimalarials in the outgoing treatment guidelines (SP in particular).

Indicator 3. Percentage of encounters with patients diagnosed with uncomplicated malaria in which they were prescribed quantities of appropriate antimalarials sufficient to complete a full course of treatment

Description and Use of the Indicator

The affordable and widely available antimalarial chloroquine that was in the past a mainstay of malaria control is now ineffective in most malaria-endemic areas because of increased resistance to the therapy by malaria parasites. In addition, resistance to previously used second-line medicines, such as SP, is increasing rapidly. A key recommended strategy in malaria control to slow down the spread of resistance is that patients complete the full course of pharmaceutical therapy prescribed for them. Before patients can complete a full course of treatment, the health worker must not only prescribe the right medicines, but also prescribe them in the right quantities. The national malaria treatment guidelines provide the definition of a full course of treatment.

This indicator measures the extent to which patients suffering from uncomplicated malaria or their caregivers are prescribed sufficient medicines by the health facility or retail pharmaceutical outlet to complete a full course of treatment. High percentages identify a positive behavior that should be reinforced or encouraged. Low percentages identify the need for improvement. Low percentages could indicate that patients do not complete a course of treatment. This behavior could have potentially serious consequences for the patient as well as contributing to drug resistance.

Methodology

Data for this indicator were collected through a survey of 48 health facilities (40 public or mission and 8 private) as well as 32 retail pharmaceutical outlets. A minimum sample size of 10 exit poll interviews per health facility was used to determine the type and quantity of prescribed antimalarials prescribed to patients with uncomplicated malaria. In addition, 32 simulated purchases were conducted in retail pharmaceutical outlets to determine the quantities of medicines prescribed in comparison to national treatment guideline recommendations.

Results

For 40 public sector health facilities (MoH and mission), data for a sample of 476 exit poll interviews showed that an average of 71.3 percent of prescriptions presented were for quantities sufficient for a full course of treatment, with a range from 42 percent to 88 percent. For private health facilities, data for a sample of 120 exit poll interviews showed that an average of 59.2 percent of prescriptions presented were for sufficient quantities of treatment for malaria. For 32 retail pharmaceutical outlets, an average of 77.3 percent of malaria prescriptions or recommendations were for quantities sufficient for a full course of treatment.

Table 5. Percentage of Encounters Diagnosed as Uncomplicated Malaria and Prescribed Adequate Quantities of Appropriate Antimalarials to Complete a Full Course of Treatment

Facility Type	Total Number of Facilities/ Outlets Surveyed	Total Number of Exit Poll Interviews/ Simulated Purchases per Facility/ Outlet	Makueni	Kwale	Bondo	Kisii
District Hospital	4	41	85%	58%	51%	80%
Mission Hospital	4	40	66%	73%	71%	77%
Health Center	16	186	42%	65%	52%	78%
Dispensary	16	167	85%	82%	88%	88%
Private Clinic	8	42	87**%**	59%	100%	74%
Private Pharmacy	32	32	67%	100%	67%	75%
Overall	**80**	**508**	**68.7%**	**72.8%**	**71.5%**	**78.7%**

Discussion

Analysis showed that overall the majority of patients diagnosed with uncomplicated malaria were prescribed adequate quantities of appropriate antimalarials for their respective age groups. It can be argued that a full course of treatment for both SP and amodiaquine (first- and second-line treatments for uncomplicated malaria) are fairly well known to both health personnel and patients/caregivers, and because of the short duration of treatment with these medicines and the relatively low costs associated with purchasing complete doses, the finding that most encounters surveyed received a complete course of treatment is not surprising. When the use of artemether-lumefantrine begins in September 2006 following the policy launch, the MoH will have to closely monitor this indicator to ensure compliance with the policy and the resulting prevention of resistance development.

The finding that 72.9 percent of encounters were prescribed an appropriate antimalarial in the pharmaceutical retail outlets is also encouraging, because it means that the retail outlets are not only interested in selling antimalarials that will provide them a high profit margin but also in providing treatments that are nationally recommended.

Indicator 4. Percentage of prescribed antimalarial medicines actually dispensed by health facilities

Description and Use of the Indicator

This indicator measures the ability of health facilities to dispense the prescribed antimalarial medicines to malaria patients or caregivers of malaria patients. Medicines that are actually dispensed are defined as prescribed antimalarial medicines that are dispensed from the health facility. Theoretically, all, or 100 percent, of medicines prescribed should be dispensed. Low percentages identify problems of availability or poor dispensing practices. This indicator is based only on the prescriptions for antimalarials presented for dispensing at health facilities.

Methodology

Using the same data sample for exit poll interviews as was used for Indicator 3, information on the number of medicines dispensed compared to the total number of medicines prescribed was ascertained in 48 health facilities (40 MoH and mission facilities and 8 private health facilities).

Results

An average of 92.4 percent of prescribed medicines presented for dispensing were actually dispensed, with a range of 77.6 percent to 97.9 percent.

Table 6. Percentage of Prescribed Antimalarials That Were Actually Dispensed at the Health Facility

Facility Type	Number of Antimalarial Medicines Prescribed	Number (%) Dispensed as Prescribed
District Hospital	112	87 (77.6%)
Mission Hospital	63	59 (93.6%)
Health Center	452	478 (94.6%)
Dispensary	448	362 (80.8%)
Private Clinic	87	88 (97.9%)
Overall	**1,162**	**1,074 (92.4%)**

Discussion

As can be seen in Table 6, the majority of patients received their medicines as prescribed. These data, however, have limitations because the prescription may not be presented if the patient/caregiver has no money, has medicines at home, or prefers to go to the retail sector.

Indicator 5. Percentage of patients/caregivers who could correctly describe how to take/give the prescribed antimalarial medication

Description and Use of the Indicator

Ideally, every patient and caregiver should know the name of the medicines prescribed to them, what the medicine is prescribed for, the dose and frequency, how to administer the medicine, and the number of days for which the medicine should be taken. However, a few key items are more critical than others. To correctly describe how to take or give the medication, the patient or caregiver should know the dose to administer, how many times a day, for how many days, and how to administer. All four of these items should be mentioned verbally by the patient/caregiver during the survey encounter.

The indicator used here is useful to measure the potential for nonadherence and possible treatment failure, resulting from a lack of knowledge by patients and caregivers on how to administer medication correctly. It measures the effectiveness of communication between the health care worker and the patient. A low percentage indicates that health workers are not providing enough information to patients/caregivers about the medication, which could be a reason for nonadherence to treatment. The desired change over time is an increase in the indicator.

Methodology

This indicator was calculated using data from exit poll interviews of patients/caregivers needing curative care for malaria in each health facility, who were asked to describe how they are going to take/give the medicines prescribed.

Results

In a sample of 48 health facilities (40 MoH and mission facilities and 8 private health facilities), 476 antimalarial prescriptions surveyed showed that an average of 79.4 percent of patients/caregivers could describe correctly how to take/give the medication.

Table 7. Percentage of Patients/Caregivers That Could Correctly Describe the Administration of Their Prescribed Antimalarials

Facility Type	Number of Antimalarial Prescriptions Surveyed	Administration Correctly Described by Patient/Caregiver (%)
District Hospital	41	27 (65.8%)
Mission Hospital	40	39 (97.5%)
Health Center	186	128 (68.8%)
Dispensary	167	143 (87.6%)
Private Clinic	42	41(97.6%)
Overall	**476**	**378 (79.4%)**

Discussion

The results show a generally high percentage of patients/caregivers who knew how to correctly take/give prescribed medication; therefore, a good chance exists that the medicines will actually be administered correctly. This finding could be because the patients are given good information by the prescribers or have previous knowledge of the antimalarials given to them. Percentages were lower in the district hospitals and health centers surveyed, which might be because prescribers in those facility types are generally very busy. An overwhelmingly large number of patients visit those facilities, and prescribers might not have enough time to adequately counsel their patients and explain properly to them how to administer the medication prescribed. This behavior could lead to nonadherence and treatment failure.

Private and mission health facilities had higher percentages of patient/caregivers who could correctly describe how to take/give prescribed medication as instructed by the health worker. This finding is probably caused by the fact that private and mission hospitals see fewer patients and therefore health workers can take more time to communicate with patients/caregivers receiving malaria treatments.

This indicator, although used, is deemed to be somewhat subjective because the responses elicited from the patients/caregivers upon leaving the facility do not indicate how the medications will actually be administered in the home.

Indicator 6. Percentage of health workers and retail pharmaceutical outlets that provided some information to patient/caregivers on how to take/give the recommended medicines

Description and Use of the Indicator

This indicator measures whether health workers are able to communicate to patients how to take their medication. This component is important in gaining an understanding of patient use of medication and patient education. The definition for "some information" includes the dose and the frequency of medication use, how to prepare the medicines, whether to take the medicine with food, or any potential side effects or symptoms associated with the medicine. If the health worker explains at least one of these aspects to the patient, then, for this indicator, the health worker is considered to have provided some information regarding the prescribed medicine. Failure to directly discuss any of these issues with the patient is considered as not providing any information.

Methodology

This indicator was calculated using observation data from consultations of patients/caregivers needing curative care for malaria in each health facility and by a determination of prescribing practices in retail pharmaceutical outlets through simulated purchases.

Results

As can be calculated from the information in Table 8, in a survey of 40 public sector health facilities, an average of 42.9 percent of health workers provided some information on how to take/give the recommended medicines; an average of 100 percent of health workers in private health facilities provided some information; and an average of 50 percent of prescribers in retail pharmaceutical outlets provided some information to patients/caregivers on how to take prescribed medicines.

Table 8. Percentage of Health Workers Who Provided Information to Patients/Caregivers on How to Give the Recommended Antimalarial Medicines

Facility Type	Number of Health Workers Surveyed	Number (%) Providing Information on How to Take Medicine
District Hospital	30	14 (46.7%)
Mission Hospital	20	10 (50%)
Health Center	159	52 (32.7%)
Dispensary	139	59 (42.4%)
Private Clinic	14	14 (100%)
Retail Pharmaceutical Outlet	32	16 (50%)
Overall	**394**	**165 (49.8%)**

Discussion

The communication of information about the dosage of medicines by health workers to patients/caregivers was found to be low with the exception of in private clinics. This finding could be because the prescribers in public health facilities do not see this function as an important part of their role or that they assume that the patients already have the needed information. Malaria training among health workers in Kenya should emphasize more communication of correct content between the health worker and the patient/caregiver, particularly because AL has a much more complicated dosing regime with which patients are less familiar.

Indicator 7. Percentage of encounters with pregnant women living in malaria-endemic areas who are prescribed an appropriate antimalarial for IPT at prenatal clinics

Description and Use of the Indicator

Kenya's malaria policy recommends the administration of IPT to pregnant women for prevention of malaria. This indicator is designed to measure the extent to which pregnant women attending prenatal clinics are offered malaria medicines for IPT as described in the policy. High percentages identify a positive behavior that should be reinforced or encouraged. Low percentages identify the need for improvement.

Methodology

Data were gathered from a minimum sample of 10 prenatal encounters per health facility, and this information was used to determine the number of prescribed antimalarials.

Results

Analysis showed that in a data sample of 490 pregnant women attending health facilities, an average of 80 percent received IPT as prophylaxis for malaria. Of the women who received IPT, 100 percent received the recommended medicine in Kenya, sulfadoxine/pyrimethamine.

Table 9. Percentage of Pregnant Women Who Received IPT with SP

Facility Type	Number of Pregnant Women Surveyed	Number of Pregnant Women Who Received Prophylaxis	Number (%) of Pregnant Women Who Received Prophylaxis Who Were Given an Appropriate Antimalarial
District Hospital	41	41	41 (100%)
Mission Hospital	40	21	21 (52.5%)
Health Center	168	128	128 (76.2%)
Dispensary	161	126	126 (78.3%)
Private Clinic	80	76	76 (95%)
Overall	**490**	**392**	**392 (80%)**

Discussion

Overall, in the health facilities surveyed during the assessment, an appropriate antimalarial was prescribed for prophylaxis in prenatal encounters. Although the average percentage recorded was high, the number of pregnant women who received IPT in mission hospitals was low (52.5 percent); possible reasons include the unavailability of adequate quantities of malaria medicines and a lack of adequate education not only among mission health workers, but also among pregnant women, of the importance of IPT with SP. Communication messages should emphasize the use of IPT as a recommended measure for preventing malaria in pregnancy.

LIMITATIONS OF THE DATA

Standardized indicators to assess pharmaceutical sectors have been widely used for many years by Management Sciences for Health/Rational Pharmaceutical Management Plus and other organizations such as the World Health Organization and Pan American Health Organization. Such indicator-based studies are cost-effective tools that measure complex systems in a relatively short time and give investigators a snapshot of overall trends in the sector.

The design of the study had the following limitations—

- It was a rapid assessment and was not intended for in-depth determination of all problems identified but rather flagged the problems for the MoH to follow up on.

- The methodology used was not intended to conduct a complete assessment of the entire pharmaceutical system.

- This assessment neither measured health-seeking behavior nor patient compliance. Therefore, an understanding of the factors that influence a patient's decision to seek treatment as well as the decision to comply with the recommended treatment were not determined and would require further investigation.

- The appropriate diagnosis of malaria was not assessed.

- Only 4 of the 74 districts were sampled; therefore, these results cannot be generalized countrywide. The assessment was conducted to quickly determine what barriers exist to the efficient implementation of Kenya's new malaria treatment policy.

CONCLUSIONS, RECOMMENDATIONS, AND NEXT STEPS

Conclusions

This rapid assessment highlighted some positive findings as well as challenges in the use of antimalarial medicines in public and private sector facilities and pharmaceutical retail outlets surveyed in Kenya, as follows—

- Overall, very few facilities had at least one copy of the national treatment guidelines for malaria available. The low availability of guidelines in health facilities means that the majority of health workers do not have an available reference source that supports appropriate prescribing.

- More than half of patients or caregivers of patients with uncomplicated malaria were not prescribed an appropriate antimalarial. Health workers cannot adhere to malaria treatment guidelines if they do not know them and cannot refer to them when a diagnosis of malaria is made if no reference source is readily available.

- Approximately three-quarters of antimalarials prescribed for patients/caregivers of patients were for quantities sufficient for a full course of treatment. However, SP and amodiaquine, the recommended first- and second-line treatments for uncomplicated malaria, have a very simple dosage regimen (one dose each of three tablets), in comparison to the future recommended treatment, AL.

- The high level (over 90 percent) of dispensing by health facilities of prescriptions presented indicates the presence among health workers of good dispensing practices as well as the ready availability in health facilities of recommended medicines.

- Over 80 percent of patients/caregivers of patients could describe correctly how to take/give the prescribed antimalarial medication. However, the observation of health workers showed that less than half of them in MoH facilities provided some information to the patient/caregivers on how to take/give the recommended medicines. This finding indicates that the long-time use of SP and amodiaquine and their simple dosage regimen as well as general public education have enabled patient/caregivers to learn how to administer the recommended medications, rather than instructions from health workers.

- An average of 80 percent of pregnant women attending health facilities received IPT as prophylaxis for malaria. All the women who received IPT received the nationally recommended medicine, SP.

Recommendations

The indicators presented in the report should be viewed as the first step in a process of investigation of the problems discussed in the report. The rapid nature of this assessment did not allow for in-depth determination of the challenges identified. The findings are simply meant to help the Division of Malaria Control recognize the challenges, where they exist. Further investigation by the DOMC, using more qualitative methods, during routine monitoring and supervision is recommended to determine reasons for the challenges identified. Further investigation of the challenges will help determine why irrational prescribing, inaccurate dispensing, inappropriate patient medication counseling, and patient/caregiver nonadherence to recommended antimalarial treatments exist and which factors contribute to it.

Next Steps

As a next step and to improve the implementation of the new ACT policy, the findings highlighted in this report together with qualitative findings from DOMC routine monitoring and supervision will be used as an evidence base for discussion by key Roll Back Malaria and pharmaceutical sector stakeholders in the planned Rational Use of Antimalarial Medicines Consultative Workshop. The goal of the workshop is to design, promote, and implement realistic strategies to improve rational prescribing and dispensing of antimalarial medicines as well as use by the public and patients. The design and subsequent promotion of interventions will take into account already existing interventions, and discussions will select and target interventions where the greatest need for improvement and the greatest likelihood of achieving impact exist.

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ANNEX 1. DATA COLLECTION TEAM

Team 1	**Team 2**
Patrick Wambua (Team Leader)	Peter Mugo (Team Leader 1)
Christine Ogolla (Team Leader 2)	Joan Wakori (Team Leader 2)
Eric Were	Andrew Nyandigisi
Kenneth Bukachi	Rukia Dzombo
Abraham Komen	Roslyene Thuo
Rosemary Mutisya	Richard Miano
Halima Kariuki	Oreu Kasanju
Vicky Maiyo	Caroline Wambui

ANNEX 2. DATA COLLECTION TOOLS

DUS-1: Medical Records and Facility Review Form

General Questionnaire: Health Facilities – Hospitals/Health Centres/Dispensaries/Mission facilities

Facility Code:	**Data Collector Code:**	**Facility Type:**	
Location:	**Date:**	**Currency Used:**	**One U.S. Dollar =**

1. Does the facility have a copy of the national malaria treatment guidelines?

   Yes □ No □

   If yes, what year?_____

   Seen Yes □ No □ Where: _____

Data collected from: _____

_____

_____

DUS-1A Medical Records and Facility Review Form: Uncomplicated Malaria

Facility code:	**Data collector code:**

									Retail Outlets			
Encounter Number	**Age (Years)**	**Sex (M/F)**	**Pregnant (Yes/No)**	**Date**	**Prescriber Type**	**Medicine Name, Strength, and Dosage Form**	**Quantity Prescribed**	**Quantity Dispensed**	**Number of Unite**	**Retail Price**	**Full Course Prescribed (Yes/No)**	**Full Course Dispensed (Yes/No)**
Col. 1	**Col. 2**	**Col. 3**	**Col. 4**	**Col. 5**	**Col. 6**	**Col. 7**	**Col. 8**	**Col. 9**	**Col. 10**	**Col. 11**	**Col. 12**	**Col. 13**

DUS-1A: Use with indicators 5, 6, 7, 8, 9, 10. Data collectors should not fill out the shaded columns.

DUS-1B: Medical Records and Facility Review Form: Pregnant Women (Antenatal)

Facility code:	**Data collector code:**

									Retail Outlets			
Encounter Number	**Age (Years)**	**1st dose IPT (Yes/No)**	**Gest period**	**2nd dose IPT**	**Gest Period**	**Medicine Name, Strength, and Dosage Form**	**Quantity Prescribed**	**Quantity Dispensed**	**Number of Units**	**Retail Price**	**Full Course Prescribed (Yes/No)**	**Full Course Dispensed (Yes/No)**
Col. 1	**Col. 2**	**Col. 3**	**Col. 4**	**Col. 5**	**Col. 6**	**Col. 7**	**Col. 8**	**Col. 9**	**Col. 10**	**Col. 11**	**Col. 12**	**Col. 13**

DUS-1B: Use with Indicators 5, 6, 7, 8, 9, 10. Data collectors should not fill out the shaded columns.

DUS-2: Observation of Health Worker Data Form

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

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

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

Name, Strength, and Dosage Form	Dosage Quantity	Frequency	Duration of Treatment (Days)	Administration	Full Course Prescribed (Y/N/N Av)
Col. 1	Col. 2.	Col. 3.	Col. 4.	Col. 5	Col. 6
1. Did the health worker explain to the patient/caregiver how to take/give the medication?					Yes □ No □
2. Was the treatment consistent with STGs?					Yes □ No □
3. Did the health worker tell the care/giver patient about any signs of progressive illness and recommend a referral visit if the signs appear? (optional)					Yes □ No □
4. Was the patient treated with an ineffective antimalarial?					Yes □ No □

DUS-2: Use with indicators 6, 7, and 12 (and supplemental indicators 14, 15, 16). Data collectors should not fill out the shaded rows or columns.

DUS-3: Exit Poll Interview Form

Ask the patient/caregiver: "What was the chief complaint or the reason for the consultation (i.e., the health problem)?"

Ask the patient/caregiver: "What medicines were prescribed and how are you going to take them or give them or give them to the patient?"

Name of Medicine	Dosage Quantity	Frequency	Duration of Treatment (Days)	Administration	Did the Patient/Caregiver Receive the Medicine? (Yes/No)	Quantity Dispensed
Col. 1	Col. 2	Col. 3	Col. 4	Col. 5	Col. 6	Col. 7
Row 1: Total number of medicines prescribed						
Row 2: Can patient/caregiver correctly describe how to take/give prescribed? medications? 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 7, 8, 9, and 11. Data collectors should not fill out shaded areas.

DUS-4: Simulated Purchase Data Form for Uncomplicated Malaria in Private Pharmacies

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

Name, Strength, and Dosage Form	Dosage Quantity	Frequency	Duration of Treatment (Days)	Administration	Price	Full Course Prescribed (Y/N/N Av)
Col. 1	Col. 2	Col. 3	Col. 4	Col. 5	Col. 6	Col. 7
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: % of STG cost						

DUS-4: Use with indicators 6, 7, 10, and 12. Data collectors should not fill out shaded areas.