

**Quantification of
Artemether-
Lumefrantrine and
Other Antimalarial
Medicine
Requirements for
Year 2 of ACT
Policy
Implementation in
Kenya, July 2007**

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ACRONYMS AND ABBREVIATIONS

ACT	artemisinin-based combination therapy
AL	artemether-lumefantrine
ANC	antenatal care
DOMC	Division of Malaria Control
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
HMIS	health management information system
ITN	insecticide-treated net
IPTp	intermittent presumptive treatment in pregnancy
IM	intramuscular
IV	intravenous
JSI	John Snow, Inc.
KEMSA	Kenya Medical Supplies Agency
LMIS	logistics management information system
MEDS	Mission for Essential Drugs and Supplies
MoH	Ministry of Health
MSH	Management Sciences for Health
OPD	outpatient department
PSCM	Partnership for Supply Chain Management
RPM Plus	Rational Pharmaceutical Management Plus Program
SP	sulfadoxine-pyrimethamine
SPS	Strengthening Pharmaceutical Systems Program
USAID	U.S. Agency for International Development
USD	U.S. dollars
WHO	World Health Organization

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EXECUTIVE SUMMARY

In November 2003, following Kenya's malaria treatment policy change to the use of artemisinin-based combination therapy (ACT), the Division of Malaria Control (DOMC), with technical support from Management Sciences for Health's Rational Pharmaceutical Management (RPM) Plus Program and the KEMRI-Wellcome Trust Research Programme, estimated the required national annual quantities and costs of the first-line ACT, artemether-lumefantrine (AL), for procurement and distribution to all public health facilities (government and mission) in the country. In early 2004, with technical support from the World Health Organization, the DOMC validated the required quantities and costs of AL for the initial procurement period, July 2006 to June 2007. Overall, 12.3 million doses were procured.

With RPM Plus technical and financial support to the DOMC, an interim national system for tracking consumption of AL was put in place at the outset of AL distribution. The system was designed to establish a transparent "paper trail," or record, for receipt, storage, and issue of AL by all government and mission health facilities. It was expected that this data would be used to guide the quantification of AL at the national level for the years subsequent to policy implementation.

On July 20, 2007, with USAID Kenya funding, RPM Plus hosted a one-day quantification workshop to enable the DOMC to determine required AL quantities for Year 2 of new policy implementation, July 2007 to June 2008. In addition, a determination of quantities and costs of other antimalarial medicines was achieved for the same procurement period. Representatives were present from the DOMC, WHO, the Kenya Medical Supplies Agency (KEMSA), the Mission for Essential Drugs and Supplies (MEDS), John Snow, Inc./Partnership for Supply Chain Management (JSI/PSCM), and RPM Plus.

The methods used for quantification of AL and other antimalarials for Year 2 of ACT policy implementation were (1) the consumption-based method and (2) the morbidity based method.

Although the DOMC and its Drug Management Subcommittee recognize that the consumption-based method is the preferred method for quantifying antimalarial medicines, the use of consumption data in this particular instance was severely limited by the low AL consumption data reporting rates from public-sector health facilities and the total lack of consumption data for the other antimalarial medicines.

The following conclusions followed from the July 20, 2007, quantification exercise—

1. Artemether-lumefantrine requirements

Given the limitations of the consumption data, the authors would have liked to recommend that the estimates derived from quantification using the morbidity method (14,336,001 AL treatment doses) be used for the next procurement (for the period of July 2007 to June 2008). However, use of the morbidity-based method assumes that the treatments procured will be used rationally—and early indications are that, even in low-malaria-endemic districts implementing the new treatment policy, the management of

malaria is still imperfect, with patients for whom antimalarial medicines are not indicated in fact receiving them (DOMC 2007). Given this irrational use of AL, and the ensuing stock-outs of the first-line antimalarial medicine, it is recommended that the consumption-based method be used for procurement—that is, that the proposed quantities below are estimated with the existing consumption data adjusted to cover a full year and the entire country. Data available for calculation were AL consumption data adjusted for days out of stock, use adjustments, estimated buffer stock, losses/wastages, lead time, and procurement period. The proposed percentages by type of blister pack are based on observed consumption by age band in Kenya, as shown here.

Age Band	Basic Unit	Total Quantities
Under 3 years	Prepack tabs (6 x 1)	4,207,680
3–9 years	Prepack tabs (6 x 2)	3,146,880
9–14 years	Prepack tabs (6 x 3)	2,000,640
Over 14 years	Prepack tabs (6 x 4)	7,774,560
Total		17,128,800

These totals, if procured, will ensure that health facilities have adequate quantities of each of the individual AL treatments, preventing stock-outs and wastage.

2. Sulfadoxine-pyrimethamine requirements and costs

The total requirement for SP tablets for intermittent presumptive therapy in pregnancy (IPTp) targeting pregnant women with three doses from July 2007 to June 2008 is 8,551,006, at a cost of USD 175,296.

3. Quinine requirements and costs (for severe malaria treatment and as an alternative for those in whom AL is contraindicated or who cannot tolerate AL)

Tablets: The total requirement for quinine tablets for the procurement period of July 2007 to June 2008 is 35,978,151 tablets at a cost of USD 0.023 per tablet, totaling USD 827,498.

Injectables: The total requirement for quinine injectables for the procurement period of July 2007 to June 2008 is 977,424 ampoules at a unit cost of USD 0.0801 per ampoule, totaling USD 78,292.

4. Artemether requirements and costs

The total requirement for artemether injectables for the procurement period of July 2007 to June 2008 is 49,174 ampoules, totaling USD 51,969.20.

5. Artesunate requirements and costs

Injectables: The total requirement for artesunate injectables for the procurement period of July 2007 to June 2008 is 9,220 ampoules, at a total cost of USD 6,915.03.

Suppositories: The total requirement for artesunate suppositories for the procurement period of July 2007 to June 2008 is 5,794 ampoules, totaling USD 6,294.02.

Recommendations to the Division of Malaria Control are—

1. The low reporting rate of 19 percent within the existent AL consumption tracking system needs to be addressed if accurate and reliable AL consumption data are to be available for use in future quantification exercises. The MSH/RPM Plus/SPS-supported DOMC plan to institute a logistics management information system (LMIS) for all antimalarials should be fast-tracked. The LMIS should incorporate improvements in AL consumption tracking through the refinement and distribution of tools, achievement of an appropriate system design, and capacity building. This will ensure added efficiency in the collection, organization, and reporting of data in support of DOMC decision making and quantification.
2. While efforts are being made to achieve passive reporting of AL and other antimalarial medicines consumption, it is further recommended that active data collection be achieved on the consumption of antimalarial medicines and other commodities, including diagnostics and insecticide-treated nets. Active data collection can be accomplished through the institution of an annual survey to collect consumption data at the facility level. This would feed into the annual Ministry of Health/Division of Pharmacy quantification exercise held in May, which determines the quantities and costs of antimalarial medicines and commodities for the upcoming fiscal year. Selected members of the Drug Management Subcommittee of the DPTWG should be invited to participate in the Division of Pharmacy quantification exercise.
3. There is a need to carry out case management trainings for Ministry of Health and mission facility health staff implementing the malaria treatment policy. Some staff have benefited from this training; however, many more remain to be trained. The authors recommend a strong focus on the rational use of medicines during upcoming case management trainings. In addition, clear direction from the DOMC to health facilities on how the facilities can combine doses available at hand to make up for stocked-out weight bands (DOMC 2007) and appropriate reporting within LMIS data collection tools are recommended.
4. There is a need to collect and collate data on severe malaria and patient flows within the Kenyan health care system to enable better quantification of medicines used in prereferral and in the management of severe malaria.

BACKGROUND

In 2004, the Government of Kenya made a decision to change first-line antimalarial treatment policy from sulfadoxine-pyrimethamine (SP) to artemisinin-based combination therapy (ACT) due to a precipitous decline in the clinical efficacy of SP (Amin et al. 2007). The recommended ACT for first-line therapy was artemether-lumefantrine (AL). A series of meetings was held under the auspices of the Drug Policy Technical Working Group (DPTWG) of the Division of Malaria Control (DOMC) to chart out the implementation process for the new treatment policy. One of the outcomes of the DPTWG meetings was the formation of various subcommittees to guide policy implementation under broad areas such as case management. A key group within the DPTWG, the Drug Management Subcommittee, was tasked with guiding the achievement of key pharmaceutical management actions to prepare the country for the use of ACTs. The Rational Pharmaceutical Management (RPM) Plus Program is a member of this subcommittee and, through funding from the U.S. Agency for International Development (USAID), has continued to provide technical and financial support to all activities of the subcommittee.

One of the activities of the Drug Management Subcommittee is to provide technical support to the DOMC for the estimation of antimalarial medicine quantities needed to ensure an uninterrupted supply to fully cover malaria treatment and prevention requirements for the population.

Quantification of Artemether-Lumefantrine and Other Antimalarial Medicine Requirements for Year 1 of ACT Policy Implementation

In November 2003,¹ the DOMC, with technical support from Management Sciences for Health (MSH) and the KEMRI-Wellcome Trust Research Programme, estimated the required national quantities and costs of the first-line ACT, artemether-lumefantrine, for procurement and distribution to all public health facilities (government and mission) in the country (Snow et al. 2003). Following this quantification, in early 2004, with technical support from the World Health Organization, the DOMC undertook a separate quantification of required quantities and costs. The morbidity method of quantification, which used an assumed proportion of fever cases accessing public health facilities, was used to quantify AL requirements for Year 1 of policy implementation, because there was no available consumption data for ACTs in Kenya.

In addition, quantities and costs were determined by the Ministry of Health (MoH) Division of Pharmacy for other antimalarial medicines within the national malaria treatment policy. These medicines include sulfadoxine-pyrimethamine (SP) for intermittent presumptive treatment (IPT) for pregnant women and quinine for management of uncomplicated malaria in pregnant women in their first trimester, second-line treatment, and treatment of severe malaria.

On the basis of achieved quantification estimates and costs, using funds from the Round 4 Global Fund malaria grant to Kenya, two orders of AL were procured from Novartis² in early 2006. The

¹ This was before the formation of the existent Drug Supply Management Subcommittee.

² At present, there is only a single source of artemether-lumefantrine prequalified by WHO, Coartem by Novartis.

World Health Organization office in Kenya served as procurement agent. Using Government of Kenya and Global Fund Round 2 malaria grant funds, SP, quinine, and other medicines for the management of severe malaria were procured.

Table 1 shows treatment doses of AL procured for Year 1.

Table 1. Doses of Artemether-Lumefantrine Procured for Year 1 Implementation (July 2006–June 2007)

Weight Category	Blister Pack	Quantity Procured: First Order	Quantity Procured: Second Order	Total Procured: GF Round 4	Percentage by Blister Pack Type
5 to <15 kg	6 x 1 tabs	1,073,880	2,164,590.00	3,238,470	26.32
15 to <25 kg	6 x 2 tabs	1,130,760	2,164,586.00	3,295,346	26.79
25 to <35 kg	6 x 3 tabs	1,071,360	1,297,066.00	2,368,426	19.25
Above 35 kg	6 x 4 tabs	1,548,840	1,851,150.00	3,399,990	27.64
Total doses		4,824,840	7,477,392.00	12,302,232	100

The orders of AL were received in staggered deliveries and apportioned and distributed to facilities in public and mission health sectors through the Kenya Medical Supplies Agency (KEMSA), which had a mandate to distribute 70 percent of AL received to government health facilities, and the Mission for Essential Drugs and Supplies (MEDS), which supplied faith-based health facilities with the remaining 30 percent. In addition, AL was distributed by KEMSA to other major players, such as government parastatals, universities, and community access pilot programs run by the Sustainable Healthcare Foundation (SHEF) and USAID’s Regional Economic Development Services Office (REDSO).

The determination of distribution quantities to government health facilities was based on a *smart-push*³ concept and allocations were made by the DOMC on the basis of malaria endemicity and level of health care as shown in Tables 2, 3, and 4. Table 2 shows the total numbers of each level of facility. Tables 3 and 4 show the KEMSA distribution schedule for the first and second orders of AL under the new treatment policy. Mission facilities, which usually operate by determining what type and quantity of medicines they need and by subsequently placing their orders with MEDS (*pull system*), were expected to order required quantities of AL as needed from MEDS.

³ Hospitals in Kenya and rural health facilities in select provinces operate a pull system; however, because AL was a new treatment and no consumption data existed, the DOMC and KEMSA determined the distribution quantities to the facilities.

Table 2. Number of Government Health Facilities in All Provinces of Kenya

Type of Facility ⁴	Number of Facilities
Hospitals	132
Rural health facilities	1,843
SIDA districts	248
Total	2,223

Source: KEMSA list of MoH customer facilities.

Table 3. Quantities (in Dispensers of 30 Blisters) Distributed by KEMSA to Each Health Facility: First Order

Pack Type	MH	MRHF	LH	LRHF
1 x 6 tabs	44	30	12	8
2 x 6 tabs	44	30	12	8
3 x 6 tabs	18	10	14	2
4 x 6 tabs	40	10	16	2

MH = malaria-endemic-zone hospital; MRHF = malaria-endemic-zone rural health facility; LH = low-transmission-zone hospital; LRHF = low-transmission-zone rural health facility.

Table 4. Quantities (in Dispensers of 30 Blisters) Distributed by KEMSA to Each Health Facility: Second Order

Pack Type	MH	MRHF	LH	LRHF
1 x 6 tabs	44	28	34	21
2 x 6 tabs	44	28	34	21
3 x 6 tabs	26	16	20	13
4 x 6 tabs	37	24	29	18

MH = malaria-endemic-zone hospital; MRHF = malaria-endemic-zone rural health facility; LH = low-transmission-zone hospital; LRHF = low-transmission-zone rural health facility.

The distribution of AL by KEMSA was incorporated into the agency's existing transport arrangements and delivery schedules, and as such AL was distributed to hospitals by KEMSA-contracted transporters that deliver essential medicines bimonthly to hospitals and quarterly to rural health facilities.

With RPM Plus technical and financial support to the DOMC, an interim national system for tracking AL consumption was put in place at the outset of AL distribution. The system was designed to provide a transparent record, or "paper trail," of the receipt, storage, and issue of AL by all government and mission health facilities. Daily activity registers were developed and printed for use at the facility level and were distributed nationwide with the medicines. In

⁴ Hospitals include provincial, district, and subdistrict hospitals; RHF's are health centers and dispensaries.

addition, AL summary forms were developed and distributed, and staff dispensing AL at the facility level were instructed to record the use of the medicines. At the end of every month, AL dispensed over the entire month and stocks remaining were to be summarized and this information forwarded to pharmacy staff at the district level within the first week of the following month. Pharmacy staff at the district level would in turn forward aggregated monthly summary forms to the DOMC by the tenth day of the same month, when the data would be captured in an Access database. Following data capture and analysis, reports were to be forwarded to KEMSA.

The process of AL consumption tracking was instituted by the DOMC as an interim system to use prior to the institution of a tracking system for all medicines by the MoH Division of Pharmacy. The intention of the DOMC was that the system would provide data to district pharmacists/technologists to enable them to proactively monitor and manage low and high stock levels and early-expiry medicines against average consumption at health facilities within their districts. At the central level, it was expected that data would be used to (1) advise KEMSA on resupply quantities throughout the year; (2) report against Global Fund and other drug management indicators set by the DOMC to monitor efficiency; and (3) guide subsequent quantification exercises at the national level.

Quantification of Artemether-Lumefantrine and Other Antimalarial Medicine Requirements for Year 2 of ACT Policy Implementation

On July 20, 2007, using USAID Kenya funding, RPM Plus hosted a one-day quantification workshop to enable the DOMC to determine antimalarial medicine quantities (including artemether-lumefantrine) for Year 2 of the new policy implementation (July 2007 to June 2008).⁵

Representatives were present from the Division of Malaria Control, WHO, KEMSA, MEDS, John Snow, Inc./Partnership for Supply Chain Management (JSI/PSCM), and RPM Plus.

This report summarizes the processes undertaken to achieve the quantification and the results obtained.

⁵ Prior to the workshop, the Head of the DOMC, in order to meet its GF fund disbursement schedule requirements, had to submit an order through WHO Kenya to Novartis for AL quantities required for Year 2. The DOMC requested that the quantification workshop still be conducted to properly determine the actual AL quantities needed using a methodical approach and data on hand. Due to the hurried nature of the earlier order submission, a methodological approach had not been used for AL quantity determination.

METHODOLOGY

Determining the method of quantification to use is an important part of the quantification process; medicine needs can be estimated using one or a combination of four standard methods: the consumption-based method, the morbidity-based method, the adjusted consumption method, and service-level extrapolation (MSH/WHO 1997). The method is selected on the basis of data and information available as well as the resources available for conducting the exercise. Table 5 provides a comparison of quantification methods by use, data, limitations, and assumptions.

Table 5. Comparison of Quantification Methods

Method	Uses	Essential Data	Limitations
Consumption	<p>First choice for procurement forecasts, given reliable data</p> <p>Most reliable predictor of future consumption</p>	<p>Reliable inventory records</p> <p>Records of supplier lead time</p> <p>Projected medicine costs</p>	<p>Must have accurate consumption data</p> <p>Can perpetuate irrational use</p>
Morbidity	<p>Estimating needs in new programs or disaster assistance</p> <p>Comparing use with theoretical needs</p> <p>Developing and justifying budgets</p>	<p>Data on population and patient attendances</p> <p>Actual or projected incidence of health problems</p> <p>Standard treatments (ideal, actual)</p> <p>Projected medicine costs</p>	<p>Morbidity data not available for all diseases</p> <p>Standard treatments may not really be used</p>
Adjusted Consumption	<p>Procurement forecasting when other methods are unreliable</p> <p>Comparing use with other supply systems</p>	<p>Comparison area or system with good per capita data on consumption, patient attendances, service level, and morbidity</p> <p>Number of local health facilities by category</p> <p>Estimation of local user population broken down by age</p>	<p>Questionable comparability of patient populations, morbidity, and treatment practices</p>
Service-Level Projection of Budget Requirements	<p>Estimating budget needs</p>	<p>Use by service levels and facility type</p> <p>Average medicine cost per attendance</p>	<p>Variable facility use, attendance, treatment patterns, and supply system efficiency</p>

Source: Management Sciences for Health/World Health Organization. 1997. "Quantifying Drug Requirements." In *Managing Drug Supply*. 2nd ed. West Hartford, CT: Kumarian Press.

Quantification Methodology

The morbidity and consumption methods were used by the Drug Management Subcommittee for the quantification of the following medicines within the national malaria treatment guidelines (DOMC 2006)—

1. Artemether-lumefantrine tablets
2. Sulfadoxine-pyrimethamine tablets
3. Quinine tablets
4. Quinine injectables
5. Artemether injectables
6. Artesunate injectables
7. Artesunate suppositories

Specific methodologies for quantification of AL were (1) to use imperfect consumption data available and (2) to use morbidity data. A triangulation of the methods was used to arrive at final estimates. For all the other medicines listed, the morbidity method was used for quantification, owing to the lack of consumption data. The results section of this report describes quantification steps used for each of the listed antimalarial medicines.

Processes Undertaken to Achieve the Quantification

Although the quantification workshop was a one-day event, RPM Plus and other members of the Drug Management Subcommittee undertook pre- and postworkshop activities in support of the quantification exercise.

Preworkshop activities included—

1. A series of meetings held in early July 2007 between the DOMC and RPM Plus on one hand and the DOMC and JSI/PSCM on the other hand, to evaluate the quality of the data obtained with the AL consumption tracking system. The DOMC, RPM Plus, and JSI/PSCM had already determined that the reporting rate from health facilities was very low (19 percent) and were trying to evaluate the use of the data in the existing AL consumption database for quantification. It was agreed that this dilemma be presented for discussion to other Drug Management Subcommittee members during the quantification workshop.
2. A logical analysis of the usefulness of the DOMC-collected AL data by RPM Plus on July 16, 2007. The analysis revealed wide disparities between calculations that used data from facilities with complete reporting for the review period and calculations derived using interpolated medians for non-reporting facilities.

Postworkshop activities included—

1. A presentation of the different quantification methods used during the workshop, all assumptions, and the determined estimates and costs to the head of the DOMC by the Drug Management Subcommittee. The assumptions were accepted by the DOMC head, with some additional changes.
2. A detailed final review of the quantification data and exercise as well as development of this final report. These were achieved by RPM Plus between end of July 2007 and October 2007, following a review by members of the Drug Management Subcommittee.

QUANTIFICATION EXERCISE RESULTS

Artemether-Lumefantrine Tablets

Assumptions

The main assumption made was that the estimated artemether-lumefantrine quantities would be procured using GFATM Round 4 funds and distributed by KEMSA and MEDS for use only by patients with fever presenting for malaria treatment within the formal public health sector (government and mission health facilities). This assumption will be adjusted for future AL procurements according to the funding source⁶ and implementation stage of Kenya's treatment policy rollout⁷ plan (DOMC 2005).

Other assumptions made are discussed later in this section.

Treatment Regimen

According to the national malaria treatment guidelines in Kenya (DOMC 2006), AL is the first-line recommended treatment for uncomplicated malaria for children weighing over 5 kilograms and for adults, including pregnant women in their second and third trimesters. The total recommended treatment in all listed target groups is a six-dose regimen of AL 1.5/12 mg/kg twice daily for 3 days.

For current public sector procurements of AL in Kenya, the Global Fund is the only source of funding. GFATM procurement regulations allow the purchase of only prequalified brands of AL. Coartem, a fixed-dose combination tablet of 20 mg artemether and 120 mg lumefantrine manufactured by Novartis Pharma, is currently the only WHO-prequalified brand. Four dose categories of Coartem exist, corresponding to four age categories of patients, grouped by weight. The primary (blister strip) and secondary packaging are color-coded, to help distinguish between the dose categories, as shown in Table 6.

⁶ For instance, if more funds are available to procure AL for sectors beyond the Government of Kenya and mission sectors (private-for-profit health facilities, for example), the figures will need to be adjusted upward. Such a possibility might arise owing to increased funding for malaria under initiatives such as the President's Malaria Initiative or the proposed global subsidy for ACTs.

⁷ With a July 2006 policy implementation start, in Years 1 and 2 the MoH will ensure that its government and mission health facilities (hospitals, health centers, and dispensaries) are provided with adequate supplies of AL; in Year 3 the MoH will roll out AL to the private formal sector; and in Years 4 and 5 to the retail sector.

Table 6. Presentation and Dosing Schedule for Artemether-Lumefantrine (Coartem)

Weight Category	Number of Tablets	Pack Type	Color of Packaging
5–15 kg	6	1 x 6 tabs	Yellow
15–25 kg	12	2 x 6 tabs	Blue
25–35 kg	18	3 x 6 tabs	Orange
Adult/35 kg	24	4 x 6 tabs	Green

The blister strips are packed into dispensers, each containing 30 treatment doses.

Quantification of AL Tablets Using the Consumption Method

First, the Drug Management Subcommittee calculated AL quantities using the consumption-based method. The calculation used service-level medians⁸ for missing data within the AL-consumption-tracking database. Data available for calculation were AL consumption data, days out of stock for AL, utilization adjustments, estimated buffer stock, percentage of loss/wastage, lead time, procurement period, stock in inventory, and Coartem unit costs. A review period⁹ of seven months was used.

Steps in the calculation were—

1. Calculation of average monthly consumption of AL

$$C_A = C_T \div [R_M - (D_{OS} \div 30.5)]$$

Where

- C_A = Average monthly consumption of AL, adjusted for stock-outs
 C_T = Total consumption of AL during the review period
 R_M = Review period in months
 D_{OS} = Number of days item was out of stock during the review period¹⁰

A total of 1,213 health facilities in the DOMC AL-consumption-tracking database reported consumption at least once¹¹ in the seven-month review period.

⁸ For a given month, a given level of care (for instance, dispensary), and a given AL pack size, the median consumption was derived for all reporting facilities. Any facility of the same level of care with missing data for that month was assumed to have consumed this derived median value.

⁹ The review period was October 2006 to April 2007. Although AL distribution began in July 2006, it was not until September 25, 2006, following the treatment policy launch, that health facilities started dispensing AL to patients and recording dispensed treatments in the drug activity registers.

¹⁰ Days out of stock, D_{OS} , was estimated from the average total days out of stock for each pack of AL for each service level, using data from the sentinel districts and for the same review window of October 2006 to April 2007.

¹¹ Reporting of AL consumption through the DOMC-instituted tracking system was poor, with a health-facility reporting rate of approximately 19 percent.

In order to calculate average monthly consumption, the reporting facilities were collapsed into three categories or service levels: (1) dispensary, (2) health center, and (3) hospital.

For each reporting month (e.g., October 2006), because the data were highly skewed and a mean would not be informative, the median consumption for the month for each level (e.g., dispensary) was calculated. The calculated median for each month was extrapolated to the same service level (e.g., dispensary) where there was missing data.

For each pack size of AL, consumption for the seven-month period was calculated from a mixture of extrapolated medians (for missing values) and reported consumption where available.

The average monthly consumption calculation yielded the results shown in Table 7.

Table 7. Average Monthly Consumption of Artemether-Lumefantrine by Pack Type and Facility Type (n = 1,213)*

Pack Type	Hospitals	Health Centers	Dispensaries
6 x 1 tabs	11,965	15,141	33,519
6 x 2 tabs	7,393	12,664	25,293
6 x 3 tabs	4,129	8,675	16,031
6 x 4 tabs	20,115	35,386	56,548

*Of the 1,213 health facilities with some form of reporting for AL in the review period, 88 (7.3%) were hospitals, 243 (20.0%) were health centers, and 882 (72.7%) were dispensaries.

2. Calculation of the projected average monthly consumption of AL

$$C_P = C_A + (C_A \times A_U)$$

Where

C_P = Projected average monthly consumption

C_A = Average monthly consumption

A_U = Utilization adjustment

In 2006, KEMSA distributed AL to a total of 2,223 health facilities in Kenya. In the procurement period for which the quantification was done (July 2007 to June 2008), it is planned that the KEMSA list of MoH client facilities will expand by 1,000 facilities. Because this quantification also covers facilities supplied by MEDS (30 percent of all public health facilities), adjustment to the average monthly consumption was calculated for each Coartem pack size,¹² as shown in Table 8. The total number of public health

¹² Simple direct proportionality was used to extrapolate data from 1,213 to 4,604 facilities. The distribution of facilities inherent in the 1,213 facilities was assumed to apply to the 4,604 facilities. For example, if average monthly consumption of the 6 x 1 pack for 88 hospitals is 11,965, that for hospitals countrywide would be $11,965 \times (4,604 \times 7.3/100) / 88$, which is approximately 45,700.

facilities to be served were calculated on the assumption that whatever their number, 70 percent would be MoH and 30 percent mission. In 2006, 2,223 facilities were MoH, and it is anticipated that these will grow by 1,000 making a total of 3,223 MoH facilities. Because this constitutes 70 percent of facilities, for a 100 percent coverage, total facilities will be $3,223 \times 100\% / 70\% = 4,604$ MoH and mission facilities.

Table 8. Projected Average Monthly Consumption of AL by Pack Type and Facility Type*

Pack Type	Hospitals	Health Centers	Dispensaries
6 x 1 tabs	45,700 (11,965)	57,377 (15,141)	127,209 (33,519)
6 x 2 tabs	28,237 (7,393)	47,991 (12,664)	95,991 (25,293)
6 x 3 tabs	15,771 (4,129)	32,874 (8,675)	60,840 (16,031)
6 x 4 tabs	76,829 (20,115)	134,097 (35,386)	214,608 (56,548)

*Projected 4,604 facilities.

3. Calculation of the safety/buffer stock needed for each product

$$SS = C_P + S_P$$

Where

- SS = Safety stock
- C_P = Projected average monthly consumption
- S_P = Safety stock period in months

The overall safety stock required was calculated using the total projected average monthly consumption for all targeted facilities.

4. Calculation of the quantity of each dosage pack required in the specified procurement period

$$Q_O = [C_P \times (LT + PP)] + SS - (S_I + S_O)$$

Where

- Q_O = Quantity required in basic units, before adjustment for losses (see Table 9)
- C_P = Projected average monthly consumption in basic units
- LT = Lead time, in months
- PP = Procurement period, in months
- SS = Safety stock, in basic units
- S_I = Stock in inventory, in basic units¹³
- S_O = Stock on order¹⁴

¹³ Stock in inventory, S_I, was assumed to be zero.

¹⁴ Stock on order, S_O, was assumed to be zero.

Table 9. Quantity of AL Treatment Doses Required Monthly, Before Adjustment for Losses, by Pack Type and Facility Type

Pack Type	Projected Average Monthly Consumption	Safety Stock	Treatment Doses Required Monthly, Before Adjustment for Losses
Hospitals			
6 x 1 tabs	45,700	182,800	913,998
6 x 2 tabs	28,237	112,949	564,746
6 x 3 tabs	15,771	63,082	315,411
6 x 4 tabs	76,829	307,314	1,536,570
Health Centers			
6 x 1 tabs	57,377	229,509	1,147,547
6 x 2 tabs	47,991	191,963	959,814
6 x 3 tabs	32,874	131,497	657,484
6 x 4 tabs	134,097	536,386	2,681,930
Dispensaries			
6 x 1 tabs	127,209	508,838	2,544,188
6 x 2 tabs	95,991	383,962	1,919,811
6 x 3 tabs	60,840	243,360	1,216,799
6 x 4 tabs	214,608	858,431	4,292,154

5. Adjustment for losses and program changes

$$Q_A = Q_O + (Q_O \times \% \text{ adjustment for losses and program changes})$$

Where

Q_A = Quantity to order in basic units, after adjustment for losses

Q_O = Quantity required in basic units, before adjustment for losses

The Drug Management Subcommittee used an adjustment of 5 percent for losses and wastage. In addition, data from the 2006 HMIS report (National Bureau of Statistics 2006) indicates an overall decrease of 13 percent, from the previous year's report, in outpatient malaria cases. This decrease can be attributed to the general success of malaria control interventions in Kenya and the use of ITNs in particular. The Drug Management Subcommittee accordingly made an adjustment of 13 percent to reflect the change in program goals made in response to the report.

6. Conversion of quantity of Coartem to order from basic units into shipment packages and estimation of costs for each product

This process took into consideration the four Coartem package sizes, Novartis packaging and calculated minimum order quantities.

Table 10 summarizes the final quantities and costs derived from the quantification exercise

Table 10. Quantity of AL Treatments Required by Pack Type After Adjustment for Losses and Program Changes

Pack Type	Doses Required Over 12-Month Procurement Period	Doses Required, Adjusted for Losses (5%)	Adjustment Due to Program Change (13%)	Min. Cartons Required = Doses in Multiples of 480	Adjusted No. Treatments Based on Min. No. Cartons Required	Cost per Unit of Treatment (USD)	Total Cost* (USD)
6 x 1 tabs	4,605,733	4,836,019	4,207,337	8,766	4,207,680	0.45	1,893,456
6 x 2 tabs	3,444,370	3,616,589	3,146,432	6,556	3,146,880	0.90	2,832,192
6 x 3 tabs	2,189,694	2,299,179	2,000,286	4,168	2,000,640	1.35	2,700,864
6 x 4 tabs	8,510,655	8,936,188	7,774,483	16,197	7,774,560	1.80	13,994,208
Total	18,750,452	19,687,975	17,128,538	35,685	17,128,800		21,420,720

* The total cost requirement listed is exclusive of procurement agent handling charges, budgeted at 3% of the cost of the commodities, and local distribution costs, which will vary depending on KEMSA and MEDS charges.

Quantification of AL Tablets Using the Morbidity Method

After calculating AL quantities using the consumption-based method, the Drug Management Subcommittee calculated quantities using the morbidity-based method. The calculation used fever cases in the public health sector. Data available for calculation are summarized in Table 11.

Table 11. Information/Data Used and Sources for Quantification of AL Tablets Using the Morbidity Method

Information	Data			Sources
National Malaria Treatment Policy and Treatment Guidelines for Malaria (MoH 2006)	First-line treatment for children over 5 kg, adults, and pregnant women in the second and third trimesters			Division of Malaria Control
Percentage of treatment failure to first-line medication	5%			Kenya antimalarial drug efficacy study (Falade et al. 2005)
National population data and population projections by year	36,553,000 for 2006 37,538,000 for 2007			1999 Kenya Census; World Population Prospects Population Database, United Nations Population Division
Annual population growth rate	2.65%			World Population Prospects Population Database, United Nations Population Division
Number of new fever/malaria cases reporting to public health facilities in a year	351 cases per 1,000 population in 2006			Kenya Central ¹⁵ Bureau of Statistics, 2006
Number of children <=5 and persons > 5 reporting to public health facilities in a year	Under 3 years = 36.1%; 3–9 years = 17.2%; 9–11 years = 7.5%; over 14 years = 39.2%			Case management surveys in sentinel sites, 2007, KEMRI-Wellcome Trust Research Programme
Procurement period	12 months (July 2007–June 2008)			DOMC; Procurement Agent, WHO Kenya
Strength/concentration, packaging, and costs of Coartem	Prepack 6 x 1 (6 tabs)	30 blisters per dispenser	0.45 USD per Rx/216 USD per dispenser	Novartis Pharma; WHO Global Malaria Program; <i>International Drug Price Indicator Guide</i> , 2006 Edition (MSH 2007)
	Prepack 6 x 2 (12 tabs)	30 blisters per dispenser	0.90 USD per Rx/432 USD per dispenser	
	Prepack 6 x 3 (18 tabs)	30 blisters per dispenser	1.35 USD per Rx/648 USD per dispenser	
	Prepack 6 x 4 (24 tabs)	30 blisters per dispenser	1.80 USD per Rx/ 864 USD per dispenser	
Safety stock period	3 months			DOMC
Supplier lead time	3 months			Novartis Pharma; WHO Global Malaria Program
Procurement agent charges	3%			WHO Kenya

¹⁵ Now referred to as Kenya National Bureau of Statistics.

The following step-by-step approach was taken during the morbidity-based quantification—

1. Determination of the total projected population for the procurement period (July 2007 to June 2008)

The total projected population for Kenya was recorded at 36,553,000 for 2006; it was estimated at 37,538,000 for 2007 based on an annual growth rate of 2.65 percent between 2005 and 2010 (United Nations 2007). Since the procurement is split evenly between 2007 and 2008, population data for 2007 were used for the quantification.

2. Determination of the expected number of uncomplicated cases of malaria by age band at public health facilities between July 2007 and June 2008

The annual number of outpatient department (OPD) malaria cases reported between January and December 2006 by the Kenya National Bureau of Statistics was 7,958,704 (2006). The associated facility reporting rate for this case burden of uncomplicated malaria was 62 percent. This figure was adjusted for non-reporting facilities by applying a factor of 100/62 to calculate malaria OPD cases with all facilities reporting. The total malaria OPD cases in 2006 adjusted for non-reporting was therefore 12,836,619.

For a 2006 population of 36,553,000, this case burden represents 351 cases per 1,000 population; extrapolating to 2007, the total expected malaria OPD cases would be 13,182,530. However, between 2005 and 2006, there was a 13 percent drop in malaria OPD cases (National Bureau of Statistics 2006); assuming a similar drop between 2006 and 2007, the total malaria OPD cases in 2007 would be 11,468,801.

From a recent survey¹⁶ of case management of malaria in OPDs in four sentinel districts, the age-structured burden for the various age bands for Coartem dosing was obtained as follows: under 3 years, 36.1 percent; 3 to 9 years, 17.2 percent; 9 to 11 years, 7.5 percent; over 14 years, 39.2 percent, respectively, of the total attendances. These proportions were applied to the 2007 malaria OPD case burden to derive the absolute age-structured numbers.

3. Calculation of the quantities and costs required for the procurement period (July 2007 to June 2008)

Of the malaria cases making OPD visits to public health facilities, it was assumed that 100 percent would be treated with the recommended first-line treatment, AL. Five (5) percent of these cases, 573,440 people, were likely to subsequently be put on the second-line treatment regimen, quinine tablets, due to treatment failure and/or in cases where first-line treatment is contraindicated (such as in the case of adverse drug reactions, drug interactions, or any prevailing condition preventing the use of the recommended first-line treatment).

¹⁶ Personal communication with Professor Robert Snow, Head of the Malaria Public Health and Epidemiology Group, Centre for Geographic Medicine-Research Coast, University of Oxford/KEMRI-Wellcome Trust Collaborative Programme.

The proportion breakdown was applied to the dosing schedule of the available AL brand, Coartem (Table 12), in order to determine the required treatment quantities needed.

Table 12. Dosing Schedule for Artemether-Lumefantrine (Coartem)

Body Weight	Age Group	No. of Tablets	Pack Type (Blister Unit)	No. of Tablets Recommended at Approximate Timing (Hours) of Dosing *					
				0 h	8 h	24 h	36 h	48 h	60 h
5–14 kg	Under 3 years	6	6 x 1 tabs	1	1	1	1	1	1
15–24 kg	3–9 years	12	6 x 2 tabs	2	2	2	2	2	2
25–34 kg	9–14 years	18	6 x 3 tabs	3	3	3	3	3	3
Over 34 kg	Over 14 years	24	6 x 4 tabs	4	4	4	4	4	4

* The regimen can be expressed more simply for ease of use at the program level as follows: The second dose on the first day should be given any time between 8 and 12 hours after the first dose. Dosage on the second and third days is twice a day (morning and evening).

In order to prevent any interruption of in-country availability of AL treatments, a safety stock period of three months was applied and the number of safety stock treatments calculated and added to the determined quantities.

Because each blister unit (containing complete course of treatment per age band) of AL (Coartem) is packed into dispensers, quantities were rounded off according to the minimum number of cartons¹⁷ to order, because Novartis will supply Coartem only in cartons, not in loose dispensers.

The unit costs of Coartem announced by Novartis on September 29, 2006, are—

6 x 1	= 0.45 USD
6 x 2	= 0.90 USD
6 x 3	= 1.35 USD
6 x 4	= 1.80 USD

On the basis of these prices, the total cost of Coartem requirements per age-specific blister package was calculated. In addition, WHO handling charges of 3 percent were applied to the costs to achieve a total cost for delivery of Coartem to Kenya. Table 13 summarizes the quantities and costs determined using the morbidity method.

¹⁷ Each carton of Coartem, regardless of dose-pack type, contains 16 dispenser packs, each and each dispenser pack contains 30 treatment doses.

Summary of Assumptions Made in AL Quantification Using the Morbidity Method

In summary, the following assumptions were used in the morbidity-based quantification exercise for AL tablets—

1. The HMIS data reporting rate of uncomplicated malaria is approximately 62 percent and therefore was adjusted upward by 38 percent.
2. On the basis of HMIS reporting of a 13 percent annual decrease in OPD malaria cases between 2005 and 2006,¹⁸ a proportionate decrease in OPD malaria cases was assumed between 2006 and 2007.
3. The age-structured burden of fever cases attending OPD will remain the same as that for 2006.
4. One hundred percent of cases will be given first-line treatment.
5. Buffer stock will consist of three months' supply (as recommended by the DOMC).
6. Coartem packaging will remain the same. (6 x 1, 6 x 2, 6 x 3, and 6 x 4 in cartons of 30)

¹⁸ Personal communication, Dorothy Memusi, DOMC.

Table 13. Quantities and Costs for Coartem for the Procurement Period (July 2007–June 2008)

	Population (2006)	Uncomplicated Malaria Cases Reporting to Health Facilities (2006)	Adjusted Uncomplicated Malaria Cases Reporting to Health Facilities (7,958,704*100/62) ^a	Episodes per 1,000 Population	Projected No. Cases in 2007	Projected Cases in 2007 Adjusted for Program Change (13,182,530*0.87) ^b
Malaria OPD Cases	36,553,000	7,958,704	12,836,619	351	13,182,530	11,468,801
^a Assumption 1						
^b Assumption 2						

Age Band	Malaria Cases (2007) Adjusted for Age Bands ^c	Blister Unit (Pack Type)	Number of Treatment Courses (Cases)	% of Cases Treated with Regimen ^d	Adjusted Number of First-Line Treatments	Buffer Stock (Total*3/12) ^e	Adjusted Quantity to Order (Total + Buffer)	Minimum Quantity of Cartons to Order ^f	Cost per Carton (USD)	Cost of Order (USD)
Under 3 years	4,140,237	6 x 1 tabs	4,140,237	100	4,140,237	1,035,059	5,175,296	10,782	216	2,328,912
3–9 years	1,972,634	6 x 2 tabs	1,972,634	100	1,972,634	493,158	2,465,792	5,138	432	2,219,616
9–14 years	860,160	6 x 3 tabs	860,160	100	860,160	215,040	1,075,200	2,241	648	1,452,168
Over 14 years	4,495,770	6 x 4 tabs	4,495,770	100	4,495,770	1,123,943	5,619,713	11,708	864	10,115,712
Total	11,468,801		11,468,801		11,468,801	2,867,200	14,336,001	29,869		16,116,408
^c Assumption 3										
^d Assumption 4										
^e Assumption 5										
^f Assumption 6										
							WHO handling charges			483,492
							Total cost of order			16,599,900
Note: The total requirement is exclusive of local distribution costs.										

Sulfadoxine-Pyrimethamine Tablets

Assumptions

The main assumption made was that the estimated SP quantities would be distributed by KEMSA alone for use only by pregnant women as part of intermittent presumptive treatment of malaria in pregnancy (IPTp).

Other assumptions made are included in the discussion below.

Treatment Regimen

According to the national malaria treatment guidelines in Kenya (MoH 2006), all pregnant women in areas of high malaria transmission should receive IPTp. The current recommended medicine for IPTp is SP tablets (500 mg sulfadoxine + 25 mg pyrimethamine) given as a dose of three tablets upon presentation to a health facility. The guidelines recommend that at least two doses of SP be administered, a month apart, after quickening to ensure protection against malaria. Women known to be HIV-infected or with unknown HIV status living in areas of high HIV prevalence (greater than 10 percent among pregnant women) should receive at least three doses of IPTp.

Quantification of SP Tablets Using the Morbidity Method

The Drug Management Subcommittee calculated quantities using the morbidity-based method because no consumption data exist for SP. The calculation used the number of pregnant women attending antenatal care (ANC) clinics in the public health sector. Data available for calculation were incidence of pregnancy among Kenyan women, ANC attendance rate, recommended treatment regimen for IPTp, policy regarding IPTp, and SP unit costs. The procurement period of 12 months (July 2007 to June 2008) was used for the calculations.

The following steps and assumptions were incorporated into the morbidity-based quantification exercise—

1. Determination of the projected crude birthrate for 2007

Using the crude birthrate (per 1,000 population) as an estimate of the number of pregnancies per year, the projected crude birthrate for 2007 for Kenya would be 39.2 (United Nations 2007). Because this approximation does not take into account stillbirths and pregnancy wastages, it is acknowledged to be an underestimate. The authors have therefore elected to use the upper limit of the crude birthrate (41.0, high variant) rather than the medium variant.

2. The national malaria policy targets at least two doses of SP (IPT2) to be given to pregnant women during attendance at ANC clinics and at least three doses (IPT3) to be given to pregnant women who are HIV-infected or with unknown HIV status living in areas of high HIV prevalence (greater than 10 percent among pregnant women).

3. On average, from the four DOMC sentinel sites 93 percent of pregnant Kenyan women will attend an ANC clinic once; 85 percent will attend twice; and 72 percent will attend three times during the course of their pregnancy (Gikandi et al. [in press]).
4. Based on the crude birthrate, the total projected pregnancies in Kenya, given a population of 37,538,000, will be 1,539,058.
5. A typical adult dose of SP is three tablets, each with 500 mg sulfadoxine and 25 mg pyrimethamine.
6. Assuming the proportion of pregnant women who require IPT3 according to the national recommendations is 10 percent (i.e., those who are HIV infected or with unknown HIV status living in areas of high HIV prevalence), total IPTp requirements for SP (Tsp) is defined by the following formula:

$$T_{sp} = (T_p \text{ in } 2007 \times ANC_1 \times \text{Adult dose of SP}) + (T_p \text{ in } 2007 \times ANC_2 \times \text{Adult dose of SP}) + (T_p \text{ in } 2007 \times ANC_3 \times \text{Adult dose of SP} \times W_3)$$

Where

Tsp = Total IPTp requirements for SP

Tp = Total pregnancies

ANC₁ = Proportion of pregnant women attending ANC clinic once

ANC₂ = Proportion of pregnant women attending ANC clinic twice

ANC₃ = Proportion of pregnant women attending ANC clinic three times

W₃ = Percentage of pregnant women requiring IPT3

$$T_{sp} = (1,539,058 \times .93 \times 3) + (1,539,058 \times .85 \times 3) + (1,539,058 \times .72 \times 3 \times .1) = 8,551,006$$

7. SP for the public sector in Kenya is usually packed in tins of 1,000 tablets; therefore, rounding off to the nearest thousand, the total quantity required will be 8,551 tins.
8. According to the *International Drug Price Indicator Guide* 2006 edition (MSH 2007) the median international price of a tin of 1,000 tablets of SP is 20.50 USD; therefore, the total price for 8,551 tins will be USD 175,296.
9. It is assumed that SP will be sourced from the local market and, therefore, no freight and handling charges will be incurred.

Quinine Tablets

Assumptions

The main assumption made was that the estimated quantities of quinine tablets would be procured and distributed by KEMSA and MEDS for use in MoH and mission health facilities in Kenya.

Other assumptions made are discussed later in this section.

Treatment Regimens

According to the national malaria treatment guidelines in Kenya (MoH 2006), quinine tablets 200 mg/300 mg are indicated for first-line treatment of pregnant women in their first trimester, for second-line treatment of uncomplicated malaria, and in the continuation phase of IV/IM treatment of severe malaria.

The regimens for each indication are—

- First-line treatment of pregnant women in their first trimester: Quinine tablets 600 mg every 8 hours for 7 days
- Second-line treatment of uncomplicated malaria:
 - Child dose: 10 mg/kg body weight every 8 hours for 7 days
 - Adult dose: 600 mg every 8 hours for 7 days
- Continuation phase of IV/IM treatment of severe malaria: Quinine tablets 10 mg/kg body weight every 8 hours to complete 7 days of treatment following regained consciousness from IV administration of quinine

Quantification of Quinine Tablets Using the Morbidity Method

Many pregnant women in the first trimester will be unaware of their pregnancy. It has therefore been assumed that this group of women will most likely present as outpatients in the general OPD and will be treated with first-line antimalarial medicines. The quantification for all outpatients on first-line treatment has already been covered in the previous section.

Regimens for the second-line treatment of uncomplicated malaria are—

- Child dose: 10 mg/kg body weight every 8 hours for 7 days
- Adult dose: 600 mg every 8 hours for 7 days

We have assumed that for 5 percent of outpatients presenting with fever, oral quinine will be indicated for one of these reasons: (1) treatment failure, (2) inability to tolerate first-line therapy, or (3) a contraindication to the treatment other than pregnancy.

$$\begin{aligned} \text{Total treatment failures} &= \text{Total OPD attendance for malaria} \times 0.05 \\ &= 11,468,801 \times 0.5 \\ &= 574,440 \end{aligned}$$

Quantity calculation and costs for quinine tablets for the second-line treatment can be seen in Table 14.

Table 14. Quantities and Costs for Quinine Tablets for Second-Line Treatment

Age Band *	Average Weight	Patient Load	7-Day Dose for Total Patient Load	Number of Units (Tablets)	Unit Cost (USD)	Total Cost (USD)
Under 5	20	96,506	405,324,864	2,026,624	0.023	46,612.36
5 or older	60	477,934	6,021,969,408	30,109,847	0.023	692,526.48

* Note: The two age categorizations in this and subsequent tables were informed by broad assumptions about the occurrence of severe malaria among children under five and those over five. No finer age-structured data are available to enable detailed analysis, such as was possible for AL—hence the recommendation for more formative research on patient flows within the Kenyan health system and more data on the case burden of severe malaria to inform the next iteration of this and similar quantification exercises.

Given that quinine tablets are used in the continuation phase of treatment for severe malaria, the following assumptions and steps were applied in estimating patient numbers—

1. The true burden of severe malaria is estimated based on the inpatient load at health facilities, because using the malaria incidence data will produce an underestimate.
2. Unlike for OPD patients, there is no HMIS data currently available for inpatients admitted for severe malaria management.
3. Extrapolating from a cohort of approximately 3,000 children under five years at the four sentinel sites, total admissions for 2006 stood at approximately 4.3 percent.¹⁶ We assume that 20 percent of admissions are due to severe malaria (DOMC 2007).
4. Assuming total admissions for adults for severe malaria is about one-third that of children (Adeya and Rakotoson 2005), the age-structured case burden for severe malaria in Kenya for 2007, given a population of 37,538,000, is calculated using this equation—
 - Total population x fraction of population of a given age group x total admission rate x proportion of admissions for malaria
 - For children under five years: $37,538,000 \times 0.168^{19} \times 0.043 \times 0.20 = 54,235$
 - For children five years or older: $37,538,000 \times 0.832^{20} \times 0.043 \times 0.20 \times 0.33^{20} = 88,635$

¹⁹ United Nations 2007

²⁰ Adeya and Rakotoson 2005.

5. The above patients will require a four-day dose of oral quinine, with the assumption being that by day 4, patients on severe malaria treatment are well enough to take oral quinine.

Table 15 shows oral quinine requirements for the continuation phase of treatment of severe malaria.

Table 15. Quantities and Costs for Quinine Tablets for the Continuation Phase of Treatment for Severe Malaria

Age Band	Average Weight ²¹	Patient Load	4-Day Dose for Total Patient Load	Number of Units	Unit Cost (USD)	Total Cost (USD)
Under 5	20	54,235	130,164,000	650,820	0.023	14,968.86
5 or older	60	88,635	638,172,000	3,190,860	0.023	73,389.78

The total requirement for quinine tablets for the procurement period July 2007 to June 2008 is 35,978,151 tablets at a cost of USD 0.023 per tablet, totaling USD 827,498.

Quinine Injectables

Assumptions

The main assumption made was that the estimated quantities of quinine injectables would be procured and distributed by KEMSA for use in MoH health facilities in Kenya.

Other assumptions made are discussed later in this section.

Treatment Regimens

According to the national malaria treatment guidelines in Kenya (MoH 2006), quinine injectables (300 mg/1 ml or 600 mg/2 ml ampoules) are indicated for use in the initial phase of treatment for severe malaria. The regimens for both IM and IV quinine treatment are discussed below.

²¹ Adeya and Rakotoson 2005.

Prereferral Treatment²²

IM treatment regimens for quinine are—

- Adults: A loading dose of 20 mg/kg body weight IM. Maintenance dose of 10 mg/kg body weight every 8 hours until the patient is referred.
- Children: A loading dose of 20 mg/kg body weight IM. Maintenance dose of 10 mg/kg body weight every 12 hours until the patient is referred.

Hospital Management

The regimens for IV quinine are—

- A loading dose of 20 mg/kg body weight diluted in isotonic solution to run for 4 hours.
- Maintenance dose of 10 mg/kg body weight in isotonic solution given every 8 hours to run over 4 hours. Repeat 10 mg/kg quinine infusion every 8 hours until the patient can take medication orally.

Quantification of Quinine Injectables Using the Morbidity Method

Prereferral Treatment

The case burden for severe malaria has already been discussed under the quantification of quinine tablets. For the purposes of quantifying quinine injectables for IM and IV administration, the following assumptions have been made—

1. Thirty percent of patients with severe malaria will present at a rural health facility and will warrant prereferral treatment. It is assumed that the other 70 percent will present at a higher-order facility, such as a hospital.
2. Of those requiring prereferral treatment, it is assumed that 80 percent will receive IM quinine, 8 percent will receive IM artemether, 8 percent will receive IM artesunate, and 4 percent will receive artesunate suppositories.²³
3. The weight of all those under five is assumed to be 20 kg and over fives to be 60 kg (Adeya and Rakotoson 2005).

²² Per the national malaria treatment guidelines, IM artemether, IM artesunate sodium, and artesunate rectal tabs are recommended for prereferral treatment.

²³ This is a plausible assumption and is informed by a desire to avoid being prescriptive to the DOMC and its partners; a decision has not yet been made on which of these commodities will be procured if funds are available—although it is generally agreed that artesunate is superior because of its better pharmacokinetic profile, its water solubility, and its versatility in terms of route of administration (both IM and IV).

4. It is assumed that all patients requiring prereferral treatment will be administered the medicines for a maximum of 1 day.

The total requirement of injectable quinine for prereferral management is shown in Table 16.

Table 16. Quantities and Costs for Quinine Injectables for Prereferral Management of Severe Malaria

Age	Average Weight (kg)	Patient Load	1-Day Prereferral Dose for Total Patient Load	Number of Units	Unit Cost (USD)	Total Cost (USD)
Under 5	20	13,016	10,413,120.00	17,355.20	0.0801	1,390.15
5 or older	60	21,272	63,817,200.00	106,362.00	0.0801	8,519.60

Hospital Management

All patients presenting at the hospital with severe malaria will require IV quinine. It has been assumed that patients requiring IV quinine will be managed with this medicine for a maximum of three days and will be well enough to receive oral quinine for the remaining four days of treatment.

The total requirement of injectable quinine for hospital management is can be seen in Table 17.

Table 17. Quantities and Costs for Quinine Injectables for Hospital Management of Severe Malaria

Age	Average Weight (kg)	Patient Load	3-Day Dose for Total Patient Load	Number of Units	Unit Cost (USD)	Total Cost (USD)
Under 5 years	20	54,235	86,776,000	144,627	0.0801	11,584.60
5 years or older	60	88,635	425,448,000	709,080	0.0801	56,797.31

The total requirement for quinine injectables for the procurement period July 2007 to June 2008 is 977,424 ampoules at a unit cost of USD 0.0801 per ampoule, totaling USD 78,292.

Artemether Injection, Artesunate Injection, and Artesunate Suppositories

Assumptions

Currently, none of these preparations is procured and distributed by KEMSA to health facilities. The products were, however, quantified to guide future procurements that might be undertaken through the use of donor funds.

Other assumptions made are discussed later in this section.

Treatment Regimens

According to the national guidelines (MoH 2006), the above treatments (artemether injection [80 mg/ml in adult preparations and 20 mg/ml in pediatric preparations], artesunate injection [60 mg/ml], and artesunate suppositories [200 mg in adult preparations and 50 mg in pediatric preparations]) are indicated for use in the prereferral treatment of severe malaria.

The regimens for use are as follows—

- Artemether injection: 3.2 mg/kg loading dose for both adults and pediatrics, then 1.6 mg/kg maintenance dose. The patient requires a loading dose at time 0, then a maintenance dose at 12 hours, then another maintenance dose at 24 hours.
- Artesunate injection: 2.4 mg/kg loading dose for both adults and pediatrics, then 1.2 mg/kg as a maintenance dose. The patient requires a loading dose at time 0, then a maintenance dose at 24 hours.
- Artesunate suppositories: 10 mg/kg body weight as a single dose

Quantification of Artemether Injection, Artesunate Injection, and Artesunate Suppositories Using the Morbidity Method

The total requirements and costs for these prereferral antimalarial medicines are shown in Tables 18, 19, and 20.

Table 18. Quantities and Costs for Artemether Injection (IM) for Prereferral Management of Severe Malaria

Age	Average Weight	Patient Load	1-Day Prereferral Dose for Total Patient Load	Unit Type	Number of Units	Unit Cost (USD)	Total Cost (USD)
Under 5	20 kg	1,302	166,609.92	20 mg ampoule	8,331	0.6997	5,828.85
5 years or older	60 kg	2,127	816,860.16	80 mg ampoule	40,843	1.1297	46,140.35
Total					49,174		51,969.20

Table 19. Quantities and Costs for Artesunate Injection (IM) for Prereferral Management of Severe Malaria

Age	Average Weight	Patient Load	1-Day Prereferral Dose for Total Patient Load	Number of Units	Unit Cost (USD)	Total Cost (USD)
Under 5	20 kg	1,302	93,718.08	1,562	0.750	1,171.48
5 or older	60 kg	2,127	459,483.84	7,658	0.750	5,743.55
Total				9,220		6,915.03

Table 20. Quantities and Costs for Artesunate Suppositories for Prereferral Management of Severe Malaria

Age	Average Weight	Patient Load	1-Day Prereferral Dose for Total Patient Load	Unit Type	Number of Units	Unit Cost (USD)	Total Cost (USD)
Under 5	20 kg	651	130,164	50 mg	2,603	0.9470	2,465.31
5 or older	60 kg	1,064	638,172	200 mg	3,191	1.1999	3,828.71
Total					5,794		6,294.02

LIMITATIONS OF THE EXERCISE

As is true of most quantification exercises, the accuracy of the estimates provided in this report is affected by several factors, including—

- The poor reporting rate for consumption of artemether-lumefantrine (19 percent). Because of this limitation, it was necessary to triangulate results using morbidity-based estimate comparisons.
- The lack of consumption data for other antimalarial medicines (SP and quinine). There is currently no consumption tracking system for these medicines.
- The lack of nationally representative data on patient flows in the Kenyan health system, including the proportion of patients reporting to lower-tier facilities who will require treatment before being referred to and treated at higher-order facilities (e.g., district, provincial, and national referral hospitals). Because of this gap in data, broad assumptions had to be made in conducting the exercise.
- Lack of nationally representative data on disease severity and therapeutic efficacy. It has been assumed that up to 95 percent of patients with clinical malaria will present with mild symptoms treatable in the OPD, with the remaining 5 percent requiring treatment for severe malaria.

DISCUSSION, CONCLUSIONS, AND RECOMMENDATIONS

Although the DOMC and the Drug Management Subcommittee recognize that the consumption-based method is preferred for quantifying antimalarial medicines, the use of consumption data in this particular instance was severely limited by the low reporting rates of AL consumption data from public-sector health facilities and the total lack of consumption data for the other antimalarial medicines.

Conclusions Following from the Quantification Exercise

1. Artemether-lumefantrine requirements

Given the limitations of the consumption data, the authors would have liked to recommend that the estimates derived from quantification using the morbidity method (14,336,001 AL treatment doses) be used for the next procurement (for the period of July 2007 to June 2008). However, the morbidity-based method assumes that treatments procured will be used rationally—and early indications are that, even in low-endemicity districts implementing the new treatment policy, the management of malaria remains imperfect, with patients for whom antimalarial medicines are not required receiving them (DOMC 2007). Given this irrational use of AL and the ensuing stock-outs, it is recommended that quantities derived using the consumption-based method be used for procurement, for example, as shown in the table below (figures are from Table 10 above).

Age Band	Basic Unit	Total Quantities
Under 3 years	Prepack tabs (6 x 1)	4,207,680
3–9 years	Prepack tabs (6 x 2)	3,146,880
9–14 years	Prepack tabs (6 x 3)	2,000,640
Over 14 years	Prepack tabs (6 x 4)	7,774,560
Total		17,128,800

These quantities would ensure that health facilities have adequate stock of each of the individual AL treatments, preventing stock-outs and wastage.

2. Sulfadoxine-pyrimethamine requirements and costs

The total calculated requirement for SP tablets for IPTp for the procurement period of July 2007 to June 2008 is 8,551,006, at a cost of USD 175,296.

3. Quinine requirements and costs

- Tablets: The total requirement for quinine tablets for the procurement period of July 2007 to June 2008 is 35,978,151 tablets at a cost of USD 0.023 per tablet, totaling USD 827,498.
- Injectables: The total requirement for quinine injectables for the procurement period July 2007 to June 2008 is 977,424 ampoules at a unit cost of USD 0.0801 per ampoule, totaling USD 78,292.

4. Artemether requirements and costs

- The total estimated requirement for artemether injectables for the procurement period of July 2007 to June 2008 is 49,174 ampoules, totaling USD 51,969.20.

5. Artesunate requirements and costs

- Injectables: The total requirement for artesunate injectables for the procurement period of July 2007 through June 2008 is 9,220 ampoules, at a total cost of USD 6,915.03
- Suppositories: The total requirement for artesunate suppositories for the procurement period of July 2007 to June 2008 is 5,794 ampoules, at a total cost of USD 6,294.02.

Recommendations for the Division of Malaria Control

1. The low reporting rate of 19 percent within the existent AL-consumption-tracking system needs to be addressed if accurate and reliable AL consumption data are to be available for use in future quantification exercises. The MSH/RPM Plus/SPS-supported DOMC plan to institute a logistics management information system (LMIS) for all antimalarials should be fast-tracked. The LMIS should incorporate improvements in AL consumption tracking through the refinement and distribution of tools, development of an appropriate system design, and capacity building. This will ensure added efficiency in the collection, organization, and reporting of data in support of DOMC decision making and quantification.
2. While efforts are under way to achieve passive reporting of consumption for AL and other antimalarial medicines, it is further recommended that active data collection be achieved on the consumption of antimalarial medicines and other commodities, including diagnostics and insecticide-treated nets. Active data collection can be carried out through the institution of an annual survey at the facility level. This would feed into the annual May MoH/Division of Pharmacy quantification exercise, which determines the quantities and costs of antimalarial medicines and commodities for the upcoming fiscal year. Selected members of the Drug Management Subcommittee of the DPTWG should be invited to participate in the Division of Pharmacy quantification exercise.

3. There is a need to conduct case management training for MoH and mission health staff implementing the malaria treatment policy. Some staff have already benefited from this training; however, many more remain to be trained. The authors recommend a strong focus on the rational use of medicines during upcoming case management trainings. In addition, clear direction from the DOMC is required on what health workers should do when there are stock-outs of certain AL pack sizes. The current lack of clear communication has resulted in some health workers combining certain pack sizes or even cutting up the adult packs to cater for pediatric patients (DOMC 2007). Appropriate reporting within LMIS data collection tools is also recommended.
4. There is a need to collect and collate data on severe malaria and patient flows in the Kenyan health care system to enable better quantification of medicines used in both prereferral treatment and in the management of severe malaria.
5. There is a need to generate in-country data on the therapeutic efficacy of medicines used for malaria management.

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