USAID | DELIVER PROJECT

Guidelines for Managing the Malaria Supply Chain

A Companion to the Logistics Handbook



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PRESIDENT'S MALARIA INITIATIVE

Guidelines for Managing the Malaria Supply Chain

A Companion to the Logistics Handbook

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Abstract
Guidelines for Managing the Malaria Supply Chain: A Companion to the Logistics Handbook is a practical guidebook on supply chain management with an emphasis on antimalarial health products. The text should be helpful to program managers who design, manage, and assess logistics systems for malaria programs. Policy makers, system stakeholders, and others whose jobs relate to antimalarial product supply chains will also find this guide useful.

Cover photo: A nurse explains to a mother how to give AL 2x6 (Coartem) to her baby. Chawama Clinic in Lusaka, Zambia, October 2009.

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Acronyms

AL	artemether lumefantrine
ACT	artemisinin-based combination therapy
AMC	average monthly consumption
ANC	antenatal clinic
AQ	amodiaquine (malaria)
AS	artesunate (malaria)
CBD	community-based distribution
CCM	community case management
CDC	Centers for Disease Control and Prevention
CHW	community health worker
EMEA	European Medicines Agency
FDC	fixed-dose combination
FEFO	first-to-expire, first-out
FIND	Foundation for Innovative New Diagnostics
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GMP	good manufacturing practice
HMIS	health management information system
ICS	inventory control system
IEC	information, education, and communication
IMCI	Integrated Management of Childhood Illness
IPTp	intermittent preventive treatment in pregnancy
IRS	indoor residual spraying
LLIN	long-lasting insecticide-treated bed net
LMIS	logistics management information system
LMU	logistics management unit
MDG	millennium development goals
M&E	monitoring and evaluation
MF	mefloquine
MOH	Ministry of Health

MSH	Management Sciences for Health
NEML	national essential medicines list
NMCP	National Malaria Control Program
NMSP	National Malaria Strategic Plan
OJT	on-the-job training
PMI	President's Malaria Initiative
PSM	procurement and supply management
QA	quality assurance
RBM	Roll Back Malaria
RBM-MERG	Roll Back Malaria Monitoring and Evaluation Reference Group
RDT	rapid diagnostic test
SDP	service delivery point
SOP	standard operating procedure
SP	sulfadoxine-pyrimethamine
SRA	stringent regulatory authority
STG	standard treatment guidelines
USAID	U.S. Agency for International Development
USFDA	U.S. Food and Drug Administration
WHO PQP	World Health Organization Prequalification Programme

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Introduction

Malaria causes 800 thousand to 900 thousand deaths annually, the majority of which are those of children under five in sub-Saharan Africa. In response, funding for malaria from international donors has increased significantly in recent years, and the number of initiatives focused on preventing, treating and eliminating malaria has increased. A significant component of this response has been provision of products to support this effort. The sixth Millennium Development Goal (MDG) focuses on combating HIV and AIDS, malaria and other diseases. Its targets include reduction in the incidence of malaria and the number of malaria deaths by expanding use of long-lasting insecticide-treated bed nets (LLINs) and antimalarial medicines. The MDG Achievement Fund, together with efforts by the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), the U.S. President's Malaria Initiative (PMI), the World Bank Malaria Booster Program, and others have made great strides in moving global malaria efforts from control toward elimination.[1] To make tangible progress toward elimination, malaria control programs must be performing well and should have established high coverage with appropriate vector control interventions, diagnostics, and case management services before planning for elimination.[2] Expansion of malaria programs has been accompanied by an increase in the range and volume of products, and actors involved in management of these products. Supply chains must be responsive to all of these conditions.

Resistance to common and relatively inexpensive medicines that have been used for treatment of malaria—i.e., chloroquine and sulfadoxine-pyrimethamine (SP)—created an impetus for development of new medicines and revision of guidelines. Currently, the only medicines recommended by the WHO for treatment of uncomplicated *Plasmodium. falciparum* malaria are artemisinin-based combination therapies (ACTs). These medicines combine the fast and effective action of an artemisinin derivative with a second medicine, which has a different mechanism of action and a longer half-life, prolonging *in vivo* clearance and thereby reducing risk of emergence of artemisinin-resistant malaria and preventing recrudescence.

For many years, the WHO recommended antimalarials as presumptive treatment of fever for children under five in malaria-endemic countries of sub-Saharan Africa, unless an alternative cause for the fever was diagnosed. However, in the second edition of Guidelines for the Treatment of Malaria (2010), the WHO strongly recommends parasitological confirmation for diagnosis of malaria for *all* patients, even those younger than five, before starting treatment. Microscopy or rapid diagnostic tests (RDTs) can confirm parasitological diagnosis. Although microscopy is considered the gold standard for malaria diagnosis, the accuracy and ease of use of malaria RDTs has made them especially useful and prevalent in lower-level facilities lacking equipment or trained personnel for microscopy.

Malaria products such as ACTs and RDTs have unique product characteristics that present particular logistics and program management challenges. ACTs tend to be bulky, have complicated dosing recommendations, short shelf life and an immediate street value that could be converted to cash. RDTs are also bulky and require cool storage. As RDTs are introduced more widely,

[1] Das, Pam and Richard Horton. "Malaria Elimination: Worthy, Challenging, and Just Possible." *Lancet.* October 29, 2010.

[2] Feachem, Richard GA, et al. "Malaria Elimination 1. Shrinking the Malaria Map: Progress and Prospects." *Lancet.* October 29, 2010.

community health workers (CHWs) are playing a greater role in diagnosing and treating malaria. Therefore, CHWs require training not only in testing and referring but also in logistics management of malaria products. Also, some evidence shows that where parasitological diagnosis is increasing, ACT use is decreasing. Thus, health workers and logisticians must account for availability, acceptance, and use of RDTs and ACTs when estimating their demand, which can complicate the quantification process. Furthermore, increased RDT use can impact other medicines and health services, such as referrals to health facilities for treatment of other disease conditions causing fever (e.g., antibiotics for pneumonia). These kinds of changes and other policy or contextual changes, such as subsidization of ACTs for private sector use or proliferation of substandard RDTs and ACTs in the marketplace, pose challenges for supply management.

Supply chain management of malaria products must address products, programs, and players as outlined above. These unique characteristics warrant a specific approach to logistics management of these products but not necessarily a specific or separate supply chain. Policymakers, donors, and key stakeholders must be aware that a well-functioning and integrated supply chain is important to ensure continued availability of malaria products. An integrated supply chain (rather than integration of products in a supply chain) is characterized by clarity of roles, responsibilities and processes, streamlined processes, visibility of information, trust and collaboration, and alignment of objectives. The result of an integrated supply chain is seamless linkage that connects demand and supply throughout the supply chain to serve customers better.

This document provides guidelines that focus specifically on the supply chain of malaria products. It identifies unique characteristics of these products, describes implications in managing them, and provides recommendations based on lessons learned from the field.

How to Use this Companion Piece

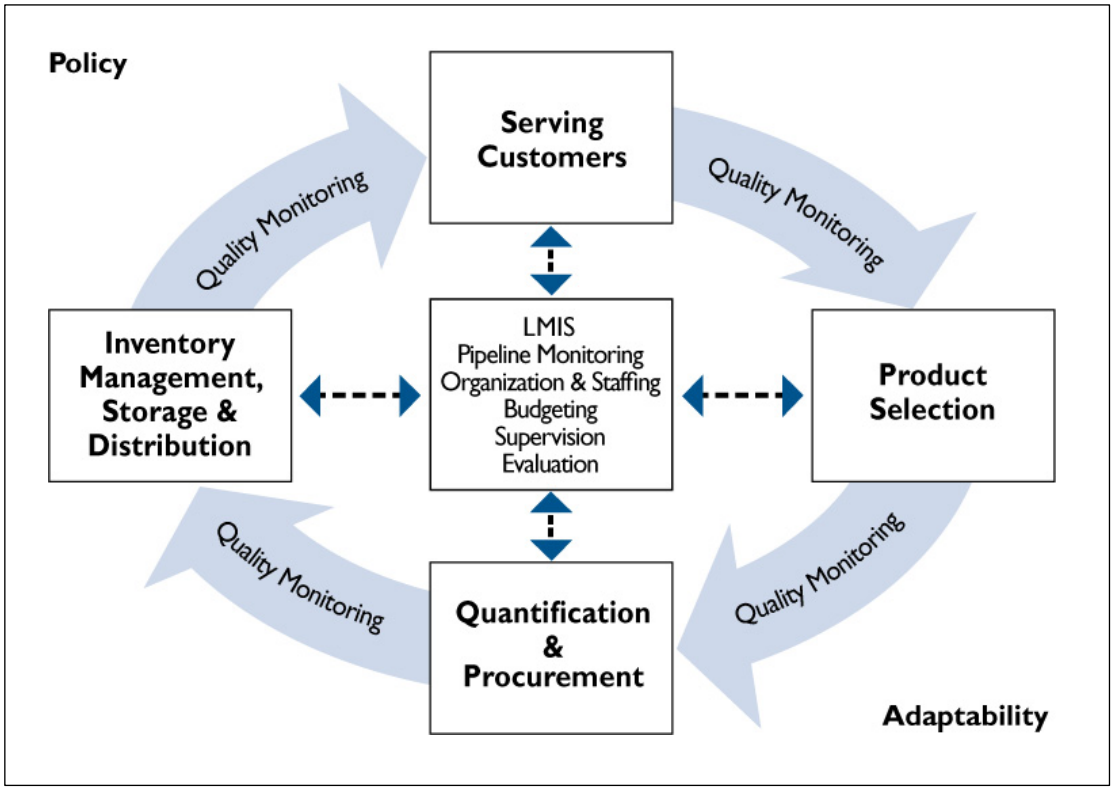
This companion piece is intended to complement *The Logistics Handbook: A Practical Guide for the Supply Chain Management of Health Commodities (2010)*[3], which provides guidance for all product categories. This companion piece provides specific logistics instructions for antimalarials such as ACTs, SP, and RDTs. It does not, however, discuss challenges and management of LLIN and insecticides or microscopic diagnosis products. Most often, these products do not usually flow through the medicines supply chain and are managed separately.

As most malaria programs are integrated with essential medicines supply chains, some recommendations in this document should take into account the impact that their implementation would have on other functions or products also managed by the system.

Over the years, logisticians have developed a model to illustrate the relationship of the activities of a logistics system. They call it the logistics cycle (see figure 1).

[3] Available on the project website under Resources/Publications as a PDF download or available in hard copy by emailing askdeliver@jsi.com.

Figure 1. The Logistics Cycle



Each chapter in this document focuses on a different element of the logistics cycle, such as Inventory Control Systems (ICSs), quantification, and storage and distribution. For each logistics area, the document cites challenges in managing antimalarials and RDTs, and provides specific recommendations to manage these products. For more detailed guidance and descriptions of each functional area discussed in these guidelines (except for Rational Use of Medicine), please see *The Logistics Handbook*.

Characteristics of Antimalarial Medicines and RDT Kits

Antimalarial medicines, particularly artemisinin-based combination therapies (ACTs) and rapid diagnostic test kits (RDTs), have special characteristics that influence how they are managed, such as shelf life, packaging, and cost. Thus, they may require special handling or modifications to the existing supply chain. Furthermore, malaria and its control have unique characteristics, such as seasonality, heterogeneous transmission, and a history of treatment provided at the community level. The particular nature of the disease, and related services and products, influence supply chain management for malaria.

This section describes important characteristics of the disease, services and products—namely ACTs, other antimalarial products, and RDTs. Based on these characteristics, subsequent chapters of this companion guide will describe recommendations for each component of the supply chain (i.e., LMIS, storage, and distribution).

I. Product Characteristics

ACTs

- **Demand:** ACTs are high demand, life-saving products that are challenging to keep in full supply. High market value increases possible diversion of products.
- **Presentation:** Available multiple formulations and presentations include fixed-dose combinations (FDCs), co-blistering, and packaging by weight bands. Various presentations must be managed separately and are often present in a single setting. Often during a stockout, these presentations may be cut or combined to provide treatment. For some presentations such as FDC artenusate/amodiaquine (AS/AQ), presentations for higher weight bands cannot be cut down for children in lower weight bands, and cutting or crushing these tablets would lead to instability and inaccurate dosages. Combining presentation of weight bands may also more than double or triple a dose if a caregiver is not careful with dosages being combined. The habit of cutting down or combining a presentation can therefore become dangerous with certain FDC ACTs.
- **Packaging:** ACTs are bulky, requiring larger storage spaces because they are typically in blister packs, often with patient information printed on the packaging. Despite recent efforts to reduce package size, ACTs require more space than other essential medicines.
- **Storage:** Room temperature storage conditions (15°C-25°C) are recommended to ensure full length of shelf life. Furthermore, due to their bulky packaging, they may require more storage space than other essential medicines.
- **Shelf life:** Most ACT formulations have a relatively shorter shelf life than other essential medicines. Recently, a manufacturer received approval from the WHO prequalification program to increase the shelf life of FDC AS/AQ to 36 months if stored below 30°C. All other ACTs have a 24-month shelf life.
- **Manufacturers:** Multiple manufacturers produce ACTs, but only a few offer finished pharmaceutical preparations approved by a stringent regulatory authority (SRA) or WHO prequalified.
- **Cost:** ACTs are significantly high value relative to most essential medicines and thus potentially more susceptible to pilferage.
- **Quality assurance:** High rates of substandard, counterfeit medicines are found in public and private sectors.
- **Availability**: ACTs are available in public and private sectors, facilities, and communities, typically by prescription, although occasionally as over-the-counter medicine.

Other antimalarials (i.e., quinine tablets, injectables and suppositories, artesunate injectables and suppositories, SP)

- **Availability:** Widely available in public and private pharmacies.
- **Use:** The WHO discourages monotherapies such as chloroquine or quinine for treatment of uncomplicated malaria, although both are often supplied for such treatment through the private sector. In the public sector, parenteral quinine and artesunate are used to treat complicated malaria, and SP is used for intermittent preventive treatment in pregnancy (IPTp). Previously, SP

was recommended for treatment of uncomplicated malaria, and in many places, people still tend to rely on it for treatment rather than ACT because they are more familiar with SP, which is significantly less expensive. Compounding these issues, health care providers in the private sector do not always receive appropriate training from the national programs and may continue to dispense other antimalarials incorrectly.

- **Kitting**: Some malaria treatments, such as those for severe malaria, are distributed in kits. These kits tend to include many different products, some of which are consumables and others durable. Therefore, kit contents tend not to be used at the same pace, often leading to wastage. Kitting may also lead to delays in procurement because kit availability is tied to the longest lead-time product in the kit.
- **Quality assurance:** High rates of substandard, counterfeit medicines are found in public and private sectors

RDTs

- **Selection:** Although the WHO and the Centers for Disease Control and Prevention (CDC) have conducted several evaluations of the efficacy of a wide variety of malaria RDTs, no official prequalification process exists. While all malaria RDTs detect *P. falciparum,* some also detect multiple species (e.g., *P. vivax*). Prices for RDTs vary widely.
- **Use:** Many health care workers do not fully trust RDT results and may not prescribe treatment based on the results. They may treat *negative* results with SP or ACT instead of having a patient leave untreated. RDTs exist in no standard format such as cassette, dipstick, or card, so a new RDT from a different manufacturer may require retraining health care providers in its use.

What About Microscopy?

Microscopy remains the gold standard for parasitological confirmation to diagnose malaria. Regardless of increased use of RDTs, microscopy will still be a key component of national lab standards for use at higher level facilities and in areas of low transmission. Consumables and chemicals used in microscopy do not usually flow through the medicines supply chain and are managed separately. For more information on management of laboratory products, please refer to *Guidelines for Managing the Laboratory Supply Chain: Version 2* at http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/GuidManaLabSC_v2.pdf

- **Storage:** RDT packaging tends to be bulky and requires larger storage spaces. Furthermore, some products require cool storage between 2°C and 30°C.
- **Shelf life:** RDTs have a relatively short shelf life of about 24 months at ambient temperatures. Shelf life varies by manufacturer and type.
- **Kitting**: Some RDTs require additional consumables such as capillary tubes and buffer solution not included as part of a kit or consumed at a different pace than other items in the kit. Thus, it may be necessary to procure these consumables separately and/or be careful to avoid wastage.
- **Waste disposal:** Testing produces waste (e.g., sharps, infectious waste) that require proper disposal.
- **Quality assurance:** Many manufacturers make RDTs, and the level of quality can vary significantly.
- **Cost:** RDTs are high cost (not value), so limiting waste and damage is critical.

II. Disease Characteristics

- **Patterns:** In terms of disease patterns and manifestations, variations can occur in prevalence, seasonality, and geographic distribution within a country and contribute to different methods used.
  - *Endemic vs. epidemic:* Based on type of exposure, the disease can have different appearances. Its endemicity may impact testing and treatments policies, and disease presentation in the population (e.g., susceptibility of patients and percentage of febrile patients with malaria). Those in turn impact supply chain functions like selection and quantification. Furthermore, recent intensive preventative measures are expected to have an impact, shifting prevalence from endemic to epidemic manifestations.
  - *Seasonality:* The disease has seasonal fluctuations in some areas, with increased cases during the rainy season.
  - *Geography:* Certain regions of a country—lower altitude, wetter, more dense foliage—may provide more hospitable environments for malaria-carrying mosquitoes. Urban areas may have a lower magnitude of transmission than rural areas.
- **Species of parasite:** Five species of the plasmodium parasite can infect humans: the most serious forms of the disease are caused by *P. falciparum,* which accounts for nearly all cases of malaria in humans. Malaria caused by *P. vivax, P .ovale,* and *P. malariae* produces milder disease not generally fatal in humans. A fifth species, *P. knowlesi*, causes malaria in macaques and can infect humans.
- **Transmission:** Disease transmission is difficult to prevent and can affect all sectors of the population. The most vulnerable groups are children under five years of age, pregnant women and the immuno-compromised, such as people with HIV and AIDS.
- **Diagnosis and incidence:** Historically and throughout sub-Saharan Africa, presumptive treatment with antimalarials has been the treatment norm as public and private health care workers in malarious regions tend to equate fever with malaria. This has made malaria incidence malaria difficult to measure accurately. In recent years, diagnostic policies have shifted from predominantly clinical to laboratory diagnosis (RDT or microscopy). The WHO recommends that before treatment begins in patients suspected of having malaria, prompt parasitological confirmation be obtained by microscopy or RDTs. Treatment based solely on clinical suspicion should be considered only when a parasitological diagnosis is not accessible.[4] As countries update guidance documents, this recommendation should become standard.
- **Manifestations of malaria:** Uncomplicated malaria is the most common form and may be intermittent or remittent, and the majority of patients can live with recurrences. However, cerebral or complicated malaria can quickly turn deadly if not treated, especially among immunologically naïve or compromised patients, making children particularly vulnerable. To prevent development of complicated malaria, the WHO recommends using ACT within 24 hours of fever's onset.[5]

[4] WHO, October 2009. http://www.who.int/malaria/publications/atoz/9789241599412/en/

[5] http://apps.who.int/tdr/publications/tdr-research-publications/rdt_round2/pdf/rdt_round2.pdf

- **Treatment:** For uncomplicated malaria, ACTs are recommended. SP is used for intermittent preventive treatment in pregnancy (IPTp). Complicated or severe malaria is often treated with injectable artesunate or quinine.
- **Drug resistance:** The plasmodium parasite can develop resistance to treatment. Resistance has developed to several antimalarials used as monotherapies, resulting in the current recommendation to use only combination therapies to treat uncomplicated malaria. When two medicines with different modes of action and thus different resistance mechanisms are used in combination, the probability of developing resistance greatly decreases. Nonetheless, resistance to treatment is a never-ending fight, and an artemisinin-resistant malaria strain has emerged along the Thai-Cambodian border.

III. Service Model Characteristics

- **Treatment guidelines:** Globally, countries are at various stages of developing and introducing testing and treatment guidelines. However, most have transitioned from monotherapies to ACTs as first-line treatment for uncomplicated malaria. Most countries are also updating their Integrated Management of Childhood Illness (IMCI) guidelines to align with WHO recommendations that confirmed diagnosis precede all treatment, even in children under five.
- **RDT policy:** Policymakers must decide where to use RDTs in their countries. They must determine the *level* of the health system—considering training, ease of use, distribution, and lab infrastructure—and the *geographic area* of the country. In highly endemic areas, using RDTs may be more cost-effective than microscopy. Rollout of RDT use may start with a pilot phase and require time to become fully established in all affected communities.
- **Simultaneous expansion of prevention efforts using LLINs and indoor residual spraying (IRS), improved diagnosis, and rapid, effective treatment:** These three streams of malaria control efforts impact each other. For example, as countries achieve targets for universal coverage with LLIN, incidence of malaria should decrease. Correct diagnosis will lead to more appropriate treatment and improved rational use, in turn decreasing cases of severe malaria. All of this will impact the type, range, and quantity of malaria products flowing through the supply chain as forecasting and quantification of each commodity are integrally related to the next.
- **Private vs. public sector:** Historically, malaria has been treated mainly through the private sector. Although this sector offers greater accessibility, service costs are higher than in the public sector whose clients may travel farther and wait longer. Furthermore, health care delivery is complicated by variations between public and private sector service delivery models due to different incentives and increasing sources of products.
- **Public-private partnerships:** Although several public-private partnership pilots have used ACTs and RDTs from the public sector to treat patients who come to the private sector with fever, successful models may be difficult to replicate (e.g., ADDOs in Tanzania or the Society for Family Health in Nigeria). Lack of reporting and accountability are the main constraints.
- **Product management at facilities:** At a given facility, malaria products may be managed in multiple locations—for example, RDTs at the laboratory and SP at the antenatal care clinic (ANC). Thus, overseeing all malaria products cohesively can be difficult. Furthermore, some of the same products may be managed at multiple locations within facility in-patient wards, out-patient dispensaries, and the main stores.

- **Range and number of facilities:** Malaria products are typically managed by most public health facilities in a country, and in many countries, thousands of such facilities may exist. The supply chain must be responsive and agile enough to deliver products to a large number of facilities, often in remote areas and representing all levels and types in the health sector.
- **Treatment:** While treatment of uncomplicated malaria can be administered at all levels of the health system, severe malaria cases are generally referred at the lower-level health facility to a higher level of care.
- **Community case management:** Recently, the community case management (CCM) package has been expanded to include prevention and treatment of malaria. Community-based health workers are increasingly diagnosing and treating malaria and may provide higher levels of care.
- **Number of partners/donors:** Management of malaria programs is very complex, with many partners and donors involved in procurement and implementation, each with unique requirements. Due in part to their high value and in part to malaria-specific funding and programs, donors expect high levels of accountability. For example, products donated by GFATM, the World Bank (WB), and PMI, each requires donor-specific reporting or other documentation.

Logistics Management Information Systems

Purpose

Information is the engine driving the entire logistics cycle. We collect information to make decisions, and the better information we have, the better decisions we can make. An LMIS comprises records and reports used to collect, organize, and report logistics data gathered across all levels of the system. Most importantly, an LMIS enables logisticians to collect data needed to make informed decisions that will ultimately expand product availability and improve customer service.

Upper-level commodity managers can use the LMIS to track trends in overall consumption and adjust national-level procurements as needed. They can identify overstocks and redistribute products. Commodity managers can also use the data to identify high levels of product expiry and then initiate action to prevent a recurrence. LMIS data can even help program managers identify incorrect prescribing or dispensing practices, or detect unusually high rates of treatment failure at a particular site or in a region. This can result in targeted supervision and improve overall quality of care for malaria.

Do not confuse an LMIS with a health management information system (HMIS). An HMIS is intended for collecting and reporting overall program parameters, such as incidence, client load, and performance. It generally collects data differently than an LMIS, whose data is specifically on managing products within the health program. In addition, the time required to collect and process data through an HMIS would mean that they are not available for timely logistics decisionmaking.

Data for Decisionmaking

Logistics systems for all products should include at least three essential data items:

- **Dispensed to user/consumption/usage:** Quantities of products given to patients for use,
- **Stock on hand:** Usable quantities of stock held at an SDP
- **Losses and adjustments:** Any quantity of stock that leaves the pipeline for reasons other than dispensation to user, such as transfers of stock from one facility to another at the same level, expiry, pilferage, or damage

The number of days out of stock at the facility is another data point useful in decisionmaking. Other data may be included in an LMIS, but an LMIS should not collect data not relevant for logistics management decisionmaking. Overloading an LMIS with such additional data creates a burden on health care personnel who implement the system and risks slowing the system and preventing timely data transmission. Therefore, a robust LMIS must

Collect data only if they will be used for making decisions!

collect only data for supply chain decisionmaking. Furthermore, forms and reports used to collect and transmit data must be easy to use.

Records and Reports

Three kinds of logistics records are typically used to collect data at points at which products are managed:

- **Consumption records** capture data about products being used or dispensed (usage logs or dispensing registers).
- **Stockkeeping records** collect information about products in storage (bin cards, stockcards, stores ledgers).
- **Transaction records** collect data on movement of stocks from one point to the other (i.e., requisition and issue vouchers, waybills).

In addition to data collection records, an LMIS must include reports, the mechanism through which logistics information is communicated from one level of the system to another. While records are used mainly to collect primary data, they typically include processed or aggregated data. The report's format and data required are driven by types and frequency of decisions to be made based on the report. In general, reports will include consolidated or aggregated consumption, stock on hand, losses and adjustments, and, frequently, days out of stock. These data will be transmitted from lower to upper levels of the supply chain.

Linking reporting and resupply encourages timely submission of reports.

Because of the link between inventory management and an LMIS, many systems use a combined LMIS report and order/request form. The advantage of combining reporting and ordering functions on the same form is that data for calculating the order are readily available. If the inventory system is a pull system, the person completing the report calculates the order; if it is a push system, the supplying facility calculates the order quantity using information in the report. Experience from other programs has shown that linking reporting and resupply encourages timely submission of reports.

In addition to reports that move up the system, feedback reports move down. In this way, lower-level facilities can appreciate how their work fits within the overall system and see that information they are submitting is being used and disseminated throughout the system. Feedback reports also give facilities information about how lower-level operations can be improved and what they could specifically be doing better (i.e., accurately completing forms in a timely manner).

Recommendations for Designing and Implementing an LMIS for Malaria Products

When designing or adapting a logistics system for malaria products, consider the burden of work at the facility level. The staff's primary responsibility there is to serve customers, and supply chain managers should design systems not too cumbersome for facility staff members, increasing the time they have to serve customers.

If the facility level is responsible for calculations, these should be as simple as possible. More complex calculations should be performed at the higher level. For example, if the quantity to

resupply is based on a complex calculation or differs at different times of the year (i.e., due to malaria seasonality), the burden of this work should be at the higher level (i.e., resupply facility).

The following recommendations consider special characteristics of malaria products. For more general information about designing and implementing an LMIS, please see *The Logistics Handbook*.

1. Use transaction records to ensure accountability.

Malaria medicines are particularly susceptible to leakage because they are high-value products needed by the general population. Transaction records provide a mechanism for ensuring product accountability and can track leakage between issuing and receiving facilities. They enable supply chain managers to detect whether quantities issued by the warehouse match those received by the facility, and to take action if discrepancies occur. Although transaction records do not prevent diversion throughout the supply chain, they can help to minimize leakage during product transportation between levels.

2. Select and consistently use the same unit of measure when reporting products.

As with all medicines and other medical supplies, data collected on dispensing registers should be recorded in the smallest unit distributed to clients. For most medicines, the recorded numbers represent numbers of tablets or capsules. However, depending on the packaging/presentation of ACTs, using AL as an example, the unit of recording could be one blister pack of 4x6 tablets. Using blister packs, rather than tablets, as the unit of measure can be a much easier way to report consumption because this is the lowest unit of issue and most commonly used for stockkeeping.

In the case of the ACT AL, blister packs come in four sizes or presentations, and the system designer must recommend guidance for facility staff on the unit of recording and reporting. One can report in terms of "tablets," but the data must be converted to the same unit. For example, if a facility has all four presentations of AL blister packs in stock—1x6, 2x6, 3x6, and 4x6 tablets—and tablets are the reporting unit, then all of these products must be converted into numbers of tablets. System designers should pay special attention to the work burden these conversions would place on the facility.

In Malawi, the unit of measure for AL selected was tablets. To help facility staff members convert the various blister pack sizes into tablets, a paper calculator was developed. This serves as a quick reference guide for converting the quantities of 1x6, 2x6, 3x6, and 4x6 blister packs into total number of tablets on hand.

Regardless of whether tablets or blister packs are selected, the same unit of measure should be used when reporting all data items—consumption, stock on hand, quantities received, losses and adjustments—for each. Some products such as AL may be reported by blister pack and others such as SP by tablet, if that is the smallest unit distributed to clients. All LMIS forms should indicate the unit of measure that should be used for each product.

For RDTs, the unit of recording and reporting should be "test." Different RDTs come in different size packages and with different kit contents. By using a unit of *test* rather than *kit* as the reporting unit, the LMIS is flexible to adapt to different RDTs. Also, over time, many programs may procure and supply various brands of RDT to facilities, so LMIS forms should not be preprinted with specific branded test names.

3. Collect and report the total number of days each product was out of stock during the reporting period.

In a logistics system, stockout data are critical for monitoring supply chain performance and highlighting supply gaps. In malaria programs, a stockout of ACTs means that a patient cannot receive treatment, which greatly increases morbidity and possibly mortality. Collecting and reporting the total number of days each product was out of stock can be used to inform resupply decisions and help to forecast future consumption more accurately. LMIS reports should include a section for the SDP to report the total number of days that each product was out of stock.

For the ACT AL, this is particularly important because of multiple blister pack sizes. Because the same formulation is in each blister pack size, a patient could still receive treatment even if the appropriate blister pack size for that patient is unavailable. For example, a patient weighting 20kg would require the 2x6 blister pack . If the patient arrives at the facility, and the 2x6 pack is out of stock, the patient may be provided the clinically correct treatment if facility staff cut a 3x6 pack or give two 1x6 packs.

If a facility reports only quantities of each blister pack dispensed but not days out of stock of each product, the facility may consistently be supplied with incorrect quantities of each blister pack required. By reporting days out of stock, the resupplying facility can calculate what consumption would have been had the product been in stock and supply the facility according to actual needs.

4. Consider using stockcards as the primary source of data for obtaining consumption data.

Consumption data is among essential data items, and various options are available for obtaining it. Many programs use a consumption record to capture data on actual quantities dispensed to patients, and these data are aggregated and included in summary reports sent to higher levels. Often for malaria programs, a dedicated dispensing register for malaria medicines does not exist. Rather, malaria medicines are captured in a general consumption record that includes all essential medicines. Aggregating consumption only for malaria medicines from such a consumption record is time-consuming and challenging, leaving significant room for error as data move from one facility to the next. If actual consumption data is required, system designers may choose to design and implement a consumption register specific to malaria products.

Two ways to use stockkeeping records to estimate consumption are described below.

1. One option is to collect consumption data using stockcards rather than a consumption record. Consumption may be calculated as follows:
    a. At the end of the reporting period, a physical inventory is conducted.
    b. This figure is subtracted from the physical inventory conducted at the end of the previous reporting period.
    c. Any receipts received during the reporting period are added.
    d. Losses and adjustments are accounted for.

The result is an estimate of consumption during the reporting period.

2. Another option is to estimate consumption using lowest-level issues data. For example, within a facility, main stocks are often kept in the store, which then issues products to the dispensary or wards. At the end of the reporting period, a facility adds all issues from the store to the dispensary/wards, providing an estimate of consumption.

Whether obtaining consumption from aggregating data on consumption records, calculating consumption from physical inventories, or using lowest level issues data, days out of stock during the reporting period should be included to determine what consumption would have been had the product been in stock.

5. Explore options for automating collection, transmission, and aggregating of logistics data from the facility level.

Demand for malaria products can fluctuate widely, due to the disease's seasonality. This fluctuation requires a responsive logistics system in which information must be available quickly and provided to the right people at the right time. The faster data are available, the sooner decisions can be made and actions taken to alleviate stock imbalances and help to assure product availability whenever needed.

A paper-based LMIS can limit responsiveness of a logistics system. In collecting data from the SDP, paper-based reports can be cumbersome, time intensive and require sophisticated calculations, reducing time that service providers spend with patients. Paper-based forms are usually sent by mail or hand-delivered, significantly increasing lead time for resupply. When the forms are hand-delivered, time with patients is further reduced. Delivery may be difficult during the rainy season when some facilities have limited accessibility. Such time delays increase higher levels' response time to understocks or overstocks at the facility level since the paper-based form must be submitted before action can be taken. Paper-based forms must be physically entered into a database, increasing the possibility of human transcription errors and requiring more time and resources. This further delays development and dissemination of routine logistics system feedback reports.

Automating some or all of an LMIS can enable service providers to spend less time collecting and reporting data and more time serving customers. Mobile phones are an alternative to help overcome some challenges of paper-based systems. These phones demonstrate a promising approach for collecting and reporting logistics data from the lowest levels and transmitting it into applications for aggregation and analysis. Using mobile phones to routinely report logistics information could facilitate overall visibility of data throughout the supply chain, from the lowest-level health facilities through the intermediate and central levels. They can allow decisionmakers to track stock status; inform prioritizing, scheduling, and content of supervisory visits; and facilitate stock transfers to address imbalances. Aggregated data could be used to more accurately forecast national-level consumption, which is necessary to develop a supply plan.

Mobile phones are not the only solution. Any initiative toward automation should be based on the spectrum of connectivity found in countries. For some facilities or areas, direct online ordering may be an option. For some, mobile phones, and for others, paper-based forms will continue to be the most appropriate format for reporting. However, at the central level, automation is critical for aggregation and analysis of national level data.

Implementation of any automation as part of an LMIS should be considered a component of logistics system design. Given the sheer number and range of public health facilities that manage malaria products, mobile phone technology may need to be phased in. So a plan to move from

paper-based LMIS to mobile phones for data collection and transmission may require implementation before nationwide coverage is possible.

6. Develop processes and mechanisms for routinely comparing services data with consumption data.

Historically, patients presenting with fever were given malaria medicines, whether or not they had malaria. Now, national roll-outs of RDTs and adoption of policies requiring a positive diagnostic test result before receipt of ACTs can help to facilitate rational ACT use. Nonetheless, routinely comparing quantities of medicines dispensed (consumption data) with episodes of malaria treated (services data) remains important. This comparison is critical for national-level quantification exercises, which calculate quantities required to keep the national pipeline full and ensure an uninterrupted supply of high-quality products to patients. This is also important information as malaria changes from an endemic to an epidemic disease in many countries. Processes should be established so malaria program and supply chain managers routinely meet to compare services and consumption data. This can be done at the time of national quantification updates.

This comparison is most useful when episodes of malaria treated are disaggregated by weight band and when quantities of ACTs dispensed are disaggregated by presentation or blister pack size.

In designing or redesigning a logistics system for malaria products, first reviewing data in the health management information system (HMIS) to determine what is and is not collected is important. If the number of episodes of malaria is collected as part of the HMIS, you need not include services data in the LMIS.

In some cases, however, system designers may want to include collection and reporting of services data on the LMIS. This decision should be informed by how data are managed at the facility level. Those who complete consumption records are usually pharmacy staff while those who complete patient records are clinical staff. It is important that information needed for the LMIS report be obtained from as few types of records and staff as possible. If services data are included on the LMIS, a separate consumption record for malaria must be developed and can include this data. For example, when patients come to collect an ACT, their visit is marked, along with a tick mark of the weight band that they represent and the quantity of medicines (by tablet or blister pack, according to unit of measure selected). These data items must then be aggregated from the consumption record and included in the routine summary report.

Some programs have developed and implemented registers that include information on RDT use and malaria medicines consumption. In small facilities or at the community level, where one staff person does virtually all activities, this may be helpful. However, at higher levels, laboratory staff tend to use RDTs while pharmacy staff manage ACTs, and these staff are rarely in the same space. Although including all malaria commodity information on one register may seem like a good approach, it is important that the supply chain manager think practically about who generates data from where at the facility.

7. For RDTs, determine what products will be included in the LMIS.

Manufacturers produce a variety of RDT brands in boxes or pouches, and contents of these kits range widely. For example, some are packaged in individual pouches and include all consumables required for administering a test. Others are packed in kits of 100 and may include only buffer solution. The products, primarily consumables, required to conduct testing include, but are not limited to, blood collection devices, lancets, cotton wool, buffer solution, and gloves.

Supply chain managers must determine which products to include as part of the LMIS—such as additional RDT buffer solution, even if it is already part of the kit. Using segmentation analysis, as described in chapter 11: System Design, system designers can decide which logistics system should manage each product and thus in which LMISs to include each product. In a system in which malaria medicines and supplies are very likely to be part of the essential medicines system, this determination may already have been made. If a laboratory commodity logistics system exists, these consumable products may be managed in that system. In this case, supply chain managers must ensure that all the products required for testing are available at the facility simultaneously. If the products are not delivered through another supply chain, it could be decided that all products required for a test would be included in the LMIS for malaria products. However, this must be done with recognition that products required for administering an RDT can be used for other purposes at the facility level. For example, gloves and cotton wool are used continually throughout the facility for a variety of reasons.

8. Collect, and if appropriate, report test results along with quantities of RDTs used.

Many countries and programs are adopting and implementing policies whereby ACTs are given only to patients who have received a positive RDT or microscopy result. At the facility level, results of RDTs should be recorded. Collecting this data allows a comparison between quantities of ACTs (treatments) consumed and numbers of positive RDTs. This comparison can indicate the level of adherence to the policy and appropriate case management, which supervisors can explore during support and supervision visits to the facility.

System designers should determine whether reporting results and numbers of RDTs to higher levels is helpful. An advantage to reporting RDT results is comparing numbers of fever episodes to numbers of diagnosed malaria episodes, which can give an estimate of incidence.

Although reporting RDT results has advantages, its usefulness has limitations. Every piece of data required on an LMIS report means more work for the facility-based staff. Collecting data on RDT results can help to determine numbers of malaria episodes, but these data will not be helpful in determining quantities of each presentation of ACT required because it is not disaggregated by weight bands.

9. On all LMIS forms, leave blank spaces to add new medicines or products.

As new technology in malaria programs develops and malaria programs grow and mature, standard treatment guidelines and protocols evolve. New packaging of existing products can emerge. LMIS forms should not require revision and reprinting whenever a new product is added to the program. To accommodate additions or changes in products used, blank spaces should be included in dispensing and usage registers and in LMIS reports so the user can write in these products if necessary. In the spirit of continuous improvement, LMIS forms should be revised and reviewed periodically to ensure that they accommodate products managed by the logistics system.

Assessing Stock Status

Purpose

Suppose you were asked to assess the stock status of a supply of RDTs in a health facility. Assume you found 100. Can you tell whether the facility has too many? Too few? Just enough? What you really want to know is how long the clinic's supply will last. Assessing stock status is determining how long current supplies will last.

To assess stock status, two pieces of data are needed:

- Stock on hand (physical inventory)
- Average monthly consumption (AMC)

To assess stock status, divide stock on hand by AMC. As a formula, it is written as:

$$\frac{\text{Stock on hand}}{\text{Average monthly consumption}} = \text{Months of stock on hand}$$

The months of stock on hand tells you how long current supplies will last, based on recent consumption. Stock status assessments are not usually written in reports at the facility level but are used to make decisions related to resupply. Depending on the ICS selected, the assessment may cause you to place an order or place an emergency order. Knowing the months of stock on hand tells whether an SDP is overstocked, understocked, or at the emergency order point. Appropriate actions should be taken based on stock status.

Stock status should be assessed regularly for each product. If you are at a higher level in the system, such as central or regional, the reported data must be adjusted to account for incomplete reporting, stockouts, or other data quality issues.

Recommendations

The following recommendations consider the special characteristics of malaria products. For more information about assessing stock status in general, please see *The Logistics Handbook*.

1. Consider cycles of demand and use of malaria products to determine what consumption data to use in calculating AMC.

For most health programs, the last three months of consumption data are used to determine average monthly consumption. However, given the seasonality of malaria transmission, consumption of malaria products is not constant throughout the year but has certain peaks of high consumption. In these cases, the last three months of data may not be indicative of consumption for the next three months. Instead of using the last three months of data to calculate AMC, other options include using:

- Last six months
- Last 12 months
- Previous month
- Last year's consumption data for the same three months

System designers should consider the local context and nature of malaria to specify what consumption data should be used to calculate AMC and to assess stock status. This decision should consider how consumption data is collected from the SDP level and how to simplify work required of SDP-level staff.

2. Consider all presentations of the product when assessing stock status.

Multiple presentations of the same product (i.e., the four presentations of AL) should be considered when assessing stock status. System designers should provide guidance on how to consider the presentations and what actions should be taken. For example, should stock status of *all* AL presentations be assessed or just that of each *presentation* of AL, or both? If the stock status of AL as a whole is determined, then the facility staff should add consumption of all AL presentations and stock on hand for all AL presentations, and then calculate the months of stock of AL rather than months of stock of each individual presentation.

Guidance must also be provided regarding actions to take based on months of stock calculated. For example, if an SDP assesses stock status for each presentation of AL and discovers that it is at the emergency order point for AL 1x6 but overstocked on AL 4x6, what actions should be taken? One option is to decide that emergency orders should be placed only when the stock status of AL as a whole has reached the emergency order point.

3. When developing guidance on actions to take based on stock status, consider the cyclical nature of malaria. If a facility is overstocked at certain times of year, no action may be necessary.

A standard operating procedure (SOP) manual for the system should provide specific guidance to staff on how to fulfill logistics tasks and responsibilities, including assessing stock status. It should provide guidance on what staff should do if they are overstocked, understocked, or at the emergency order point.

Given malaria's cyclical nature and depending on what consumption data is used to calculate AMC, an overstocked SDP may not need to take action. For most products, overstocking represents stock that may be at risk of expiry because it will not be used in time. For malaria products, however, if an SDP assesses stock status during the low season for malaria and finds itself overstocked, this may not indicate that the stock will not be used. Overstocking is less of an issue with malaria products if that stock status is assessed during the dry season. However, if a facility is overstocked during the peak malaria season, it is likely that the stock may expire before use. Procedures should be developed to facilitate stock transfers between facilities or levels to ensure that stocks do not expire.

4. Use knowledge of local malaria trends to help determine whether to place an emergency order.

Emergency orders are just that—an emergency—and emergency order procedures are not the same as routine resupply. A logistics system should have as few emergency orders as possible, since their delivery is expensive and can disrupt the designed system for routine resupply.

SDP staff are knowledgeable about trends in malaria in their geographic area. The SOP manual should specify when and how to place emergency orders. For example, procedures could be provided to SDPs that indicate when the months of stock is one month or less and that an emergency order should be placed. Although a formula can help SDP staff determine whether they are at the emergency order point, a staff should also consider malaria trends in its area if a significant quantity of supplies is needed during upcoming months. When in doubt, facility staff should contact counterparts at higher levels if they think they are risking a stockout.

Inventory Control Systems (Max-Min)

Purpose of an Inventory Control System (ICS)

An ICS informs the storekeeper—

- When to order or issue
- How much to order or issue
- How to maintain an appropriate stock level of all products to avoid shortages and oversupply

The continuous supply of quality malaria products can be guaranteed only through selection, design, and proper implementation of an appropriate ICS. Several ICSs can be designed or adopted to manage products of any kind. To manage full-supply products appropriately, a maximum-minimum ICS (also known as a max-min system) is recommended and has worked effectively.

Maximum-Minimum Inventory Control Systems

Implementation of a max-min ICS is most effective in a full-supply situation, in which sufficient quantities of all products are available to meet all needs. A max-min system allows objective resupply decisions based on need and considers established levels of safety stock, with the ultimate goal of product availability whenever needed. Given the life-saving nature of ACTs, uninterrupted product availability must be a priority.

What about rationing?
Rationing is used amid uncertainty about, or shortages in, the product supply being managed or financial resources available to purchase the products. In a rationing system, supplies are allocated according to given criteria—for instance, to serve a certain proportion of the poorest clients, to treat a certain proportion of the priority disease burden in a region, or to ensure that a certain product accounts for no more than a certain proportion of the available budget.

When designing a logistics system, a critical decision is what type of max-min (ICS) to use. There are several types, each of which has slightly different transportation, personnel training, and storage requirements. The difference among the three systems is the trigger for placing an order. Among the options are—

- **Forced ordering:** Orders are placed at regular intervals, and all products are ordered/resupplied to the maximum stock level.
  - **Delivery truck variation of forced ordering:** Rather than submitting orders to the supplying facility, a resupply truck visits SDPs at regular intervals. At the time of the visit, data are collected, and resupply quantities are determined and delivered.

- **Continuous review:** Each time a product drops to minimum stock level an order is placed to assure resupply to the maximum stock level.
  - **Two-bin variation of continuous review:** System designers determine bin sizes so one bin equals estimated consumption for one reporting period. When contents of one bin have been distributed (i.e., at the end of the reporting period), a new bin is supplied to the dispensing facility.

- **Standard:** Orders are placed at regular intervals, but a product is ordered only if it has dropped to minimum stock level. Products at the minimum stock level are ordered and resupplied to the maximum stock level.

For more detailed descriptions and discussions of the various max-min systems, please see *The Logistics Handbook*.

Pull or Push System

The designer must also decide who will determine reorder quantities. If personnel *receiving* supplies make the decision, it is a "pull" system; if personnel *issuing* supplies make the decision, it is a "push" system.

The choice of implementing a push or a pull system depends largely on in-country capacity at each level of the supply chain and availability of technology. Countries/programs with well-trained staff at lower levels or potential to train such staff adequately could easily choose a pull system. Countries/programs that rely on more trained staff or availability of computerized systems at upper levels, or those wishing to reduce the commodity management workload of lower-level staff, could choose a push system. Whichever system is selected, the right data must be available at the right place at the right time to make decisions about reorder quantities.

A Push System is Not a Rationing System!

Do not confuse "push system" with "rationing." Although push systems have historically been used when products are rationed, not all push systems are rationing systems. A true push system can be just as, or more, effective as a pull system, if data are accurate and routinely available.

Length of In-Country Commodity Pipeline

The length of the commodity pipeline, determined by adding maximum stock levels at all levels of the system, is a key consideration in commodity management. This is especially true for malaria products because most ACTs have a 24-month shelf life.

The table below illustrates the ICS components of a typical multitiered supply pipeline using a forced ordering max-min system. The numbers represent months of stock.

Table 1. In-Country Commodity Pipeline

	Lead Time Stock Level	Safety Stock Level	Review Period/ Order Interval	Min	Max	Emergency Point
Central	3	3	6	6	12	3
Regional	3	2	3	5	8	2
District	2	1	3	3	6	1
SDP	1	1	1	2	3	
Total				**16**	**29**	

Note:
Min = lead time stock level + safety stock level

Max = minimum + review period

Emergency Point = shortest lead time in case of emergency, independent of "normal" lead time

The type of max-min system (i.e., forced ordering, continuous, or standard) will affect the length of the pipeline as will other factors such as lead time and review period/order interval. The longer the pipeline—and thus the longer it takes for products to move from the central level to the client—the more safety stock required in the system. If linked to resupply, a longer pipeline means data will take more time to move from lower to upper levels.

The seasonality of malaria results in peaks and valleys of demand for ACTs and other malaria medicines. Logistics systems that manage malaria products must be as flexible and responsive as possible so adequate stock is in place to meet sharp increases in demand quickly. At the same time, too much stock should not be held in the system, given the short shelf life and high cost of many malaria products.

The following recommendations are offered for designing and implementing an ICS to manage malaria products.

Recommendations

The following recommendations consider the special characteristics of malaria products. For more information about ICSs in general, please see *The Logistics Handbook*.

1. Ensure that the length of the in-country supply pipeline accommodates the shelf life of products.

The length of the supply pipeline must accommodate the relatively short shelf lives of ACT malaria medicines, most of which are 24 months. From the pipeline described in the table above, it is clear that a 29-month pipeline is too long to manage ACTs, many of which are delivered in-country with about 75 percent of shelf life remaining. Each level in the pipeline keeps safety stock at each level, potentially tying up limited financial resources in stock quantities.

System designers may need to reduce the length of the in-country supply pipeline to accommodate these products. That pipeline can be reduced in two ways—cut the lead time, safety stock, or review period and thus influence stock levels, or reduce the number of levels in the supply chain. This is perhaps the most common strategy for ensuring relatively shorter in-country pipelines and typically the most effective in streamlining the supply chain because it brings the supply source closer to demand. In some countries, intermediate levels such as regional and/or district have been

eliminated, and products move directly from the central level to SDPs. In the table above, eliminating the district level alone would reduce the overall pipeline to 23 months, removing the regional level would reduce it to 21 months, and removing the regional and district levels would reduce it to only 15 months. Although this approach results in storage and distribution savings at these levels, more resources for transportation may be required.

Removing one or more levels from the distribution system for products does not necessarily mean removing that level for other program-related purposes such as supervision. In fact, lower-level personnel can play a critical role in overseeing program activities, monitoring product availability, and providing feedback on reporting—often more quickly and effectively than can central-level personnel.

2. Implement shorter review periods to respond to fluctuations in demand.

The shorter the review period, the more frequent the ordering and reporting. This means that program managers can respond to changes in product requirements and address stock imbalances. For example, if facilities report and are resupplied monthly, new data arrive every month, providing the staff at the higher levels "fresher" data with which to make decisions. On the other hand, if facilities report and are resupplied quarterly, higher-level staff may be less responsive to changes in consumption. Another advantage to having shorter review periods is that it limits the amount of buffer or safety stock that facilities must hold, reducing likelihood of expiry and pilferage.

However, system designers should consider advantages of quarterly reviews, meaning that higher-level staff do not have to review reports and process orders for every in-country facility every month. A longer reporting period also relieves the reporting burden on facility-level staff since they have to report less frequently. Furthermore, it can allow central-level staff more time to provide support and supervision to facility staff and to follow up with non-reporting facilities.

During the system design process, the advantages of shorter and longer review periods must be weighed when determining the appropriate reporting period and order cycle. It is always important, however, to ensure that the lead time is less than the review period.

3. Increase safety stock level so facilities can respond to fluctuations in demand.

Increasing safety stock at the SDP level will enable facility staff to respond directly to increases in consumption without facing imminent stockouts. Emergency orders will be less likely since stock will be immediately on hand. Setting the safety stock higher overall will accommodate fluctuations throughout the year rather than having to establish various system parameters that change during the rainy season.

However, increasing safety stock levels means that facilities would probably be overstocked during the dry season and raises the system's inventory carrying costs. Therefore, system designers should ensure that SDPs have sufficient storage space to accommodate a higher safety stock level and that the budget can absorb higher carrying costs.

4. Before and during peak malaria periods, consider different ways to calculate resupply.

Unlike demand for family planning products or many essential medicines, that for malaria is not constant from month to month. In addition, malaria medicines are most critical during the rainy season when some facilities may be inaccessible due to road conditions. To respond to these challenges, system designers can consider different ways to calculate resupply before and during peak demand periods for malaria products, particularly ACTs. Please note that if you decide to

calculate resupply based on different factors at different times of year, these complicated calculations should be done by the staff at the *higher* levels so as not to further burden the staff at the *facility* level.

a. Change how AMC is calculated.

Traditionally, AMC is calculated based on the last three months of consumption data. At certain times, such as just before the rainy season, this may not be indicative of what will be needed for the next review period, and facilities may be at risk out of stockout. System designers may decide to calculate AMC differently at different times of the year. Options include:

- Use three months of consumption data from 12 months ago.

During the peak of the rainy season, system designers may choose to use three months of consumption data from the previous year. For example, consider a country whose rainy season is June, July, and August. In May, using consumption data from February, March, and April may not be helpful in determining need for the next review period. Instead, consumption data from June, July, and August of the previous year may be used. This can be a good option when an automated system at the higher level is designed to do this calculation. One consideration for selecting this option is success in implementing prevention efforts. If campaigns on IRS, bednet provision, or other preventative efforts have been successful, the previous rainy season's consumption data may not be indicative of the subsequent rainy season's consumption. Furthermore, with climate change, rainy seasons are becoming less predictable, and their timing and duration can vary significantly from year to year.

- Use only last month's consumption.

If a system has been designed with a monthly review period, it is possible to only use last month's consumption as a proxy for AMC. As newer data, it can be a better indicator of what will be needed for the following review period.

- Use the last six or 12 months of consumption.

Calculating AMC using monthly consumptions for a longer period of time may account for the spike and dip in demand and be a better demand indicator than just the last three months.

b. Increase maximum stock level as lead time is longer.

During the rainy season, some facilities are inaccessible, meaning essentially that lead time is longer because delivery trucks may not be able to resupply the SDP. Consider a system with a monthly review period and a facility level max of three. At the same time, system designers know that for some facilities, they cannot receive deliveries for three months of the year. They may want to increase the maximum stock level to five for the last resupply delivery before the rainy season. This can help to ensure that facility staff have sufficient stock, even if they cannot accept deliveries. Be sure that the facility has sufficient storage space to accommodate the higher safety stock level.

5. Consider prepositioning stock before or during the rainy season at a satellite warehouse or storage facility.

Another option to enhance responsiveness of the logistics system is to preposition some stock before or during the rainy season through strategic selection of a satellite warehouse or storage facility that may be able to reach certain SDPs more quickly. This does not add a level to the system but divides the higher-level stock into another location. This is particularly important if it is known that transportation/distribution will become more difficult during the rainy season. A satellite warehouse can be especially useful if facilities do not have enough space for extra stock.

Note that these recommendations need not be implemented on a national level. Any can be region- or site-specific, so in a country where some geographic areas are malaria-free, the recommendations can be implemented only in malaria endemic areas.

Product Selection

Purpose

In any logistics system, health programs must select products for use. In a health logistics system, product selection may be the responsibility of a national formulary and therapeutics committee, pharmaceutical board, board of physicians, or other government-appointed group.

Products selected for use will impact the logistics system, so logistics requirements must be taken into account during product selection. The process is directly linked to serving customers by defining what products are procured and used in the health system and the range of products a customer can receive. Limiting the variety of products used and available at public sector facilities can make the supply chain more manageable. With a designated list of products, the central warehouse can become more familiar with the products, ensure that they meet program needs, and monitor and maintain stock levels of all products systemwide. Selecting products enables development and implementation of a national coordinated logistics system and allows redistribution of products systemwide. Furthermore, limiting types of a product such as RDTs makes it easier to train and supervise staff on its use.

Prioritizing particular products can be a tool for supply chain managers to ensure availability. Product selection facilitates access to more affordable commodity prices through economies of scale and reducing the cost of some supplies because a larger quantity of a smaller number of products is required. Selecting products is a prerequisite to quantification because it identifies products that should be quantified.

Local policies and guidelines inform the product selection process. Products are selected from or become part of a national essential medicines list (NEML), are based on standard treatment guidelines (STGs), and must be registered for overall use in-country. The next section discusses product selection in each of these three components.

National Essential Medicines List

An NEML describes medicines that satisfy priority health care needs of a population and are approved for use throughout the country. For malaria products, it can cover antimalarial medicines for uncomplicated and severe malaria, IPTp, and treatment of malaria in pregnant women. Often, countries develop NEMLs for different levels of care of the health system, based on disease patterns commonly treated at each level of the system. For example, treatment of complicated malaria may be initiated at a rural health center but completed at a district hospital.

Registration of Pharmaceutical Products

In most countries, use of pharmaceutical products requires prior evaluation and approval by a governing body often called the national drug regulatory authority (NDRA). Products to be registered should be proven effective, safe, and of good quality. Some countries also consider the product's cost or whether it is needed. Since the quality of medications is checked as part of the

registration process, each brand produced by different manufacturers is registered independently. In most cases, the product and packaging is registered.

Many pharmaceutical products may be registered for use in a country but not listed on the NEML or STGs. Products not on the NEML but used by the private sector may still be registered for use in the private sector if their efficacy, safety, and quality are acceptable to the regulatory authority.

Failure to follow pharmaceutical registration protocol could lead to customs delaying products' entry into the country. This delays delivery of important health care products, wastes time and money, and risks spoilage or expiry of products while at customs.

Standard Treatment or Testing Guidelines

STGs are suggested treatment protocols for the most optimal treatment of a specific clinical problem in a given setting, based on consensus by experts. Treatments for specific clinical problems are selected based on common diseases in the area and can vary with the level of treatment facility. Products chosen for availability at a particular facility or level of facilities should be based on STGs. These guidelines are similar in that they provide guidance for national laboratory systems on who will be allowed to perform tests, what tests should be performed, and at what laboratory level key tests should be performed.

Following STGs has significant supply chain management benefits. If health practitioners adhere to suggested treatment protocols, a smaller range of products must be available at each facility. STGs are developed based on the most effective and cost-effective treatment. If treatment providers prescribe the same product for the same condition, product demand is more predictable, facilitating more accurate forecasts. If clinicians do not follow STGs, large stockouts and/or expiries of unused medicines could result.

Changes in STGs may be warranted as new evidence on better treatments of uncomplicated and severe malaria emerge, development of resistance to ACTs arise, or countries move closer to eliminating malaria.

Recommendations for Selecting Antimalarial Medicines and RDTs

The following recommendations consider the special characteristics of malaria products. For more information about selection in general, please see *The Logistics Handbook*. Refer to Appendix A for detailed information on commonly used antimalarial medicines.

1. Choose products prequalified by an SRA or the WHO.

Given that timely and effective treatment is required to avoid malaria-related deaths and that many poor-quality antimalarials and RDTs are available globally, it is especially important that malaria products selected for use are of good quality. To avoid procurement of poor-quality medications, select products prequalified by appropriate bodies. The WHO Prequalification Program (WHO PQP) lists prequalified medicines, including several oral ACT formulations and injectable artesunate. Any antimalarials approved for use by an SRA, such as the U.S. Food and Drug Administration (USFDA) or the European Medicines Agency (EMEA) , are considered to be of good quality and acceptable for selection. Different donors may also have different prequalification requirements.

With more than 200 RDTs available in the marketplace, the WHO, in collaboration with partners, has developed an evaluation process to assess comparative performance of available RDTs.[6] It recommends using the most up-to-date evaluation and considering local conditions to select the best RDT for the country or region. The Foundation for Innovative New Diagnostics (FIND) has developed a web-based interactive tool for selection of malaria RDTs. (See Resources at the end of this chapter).

Considerations in Selecting RDTs

1. **Parasitological confirmation:** The test should detect the malaria species in the area and give reliable results for endemicity of the region (high transmission areas vs. low to moderate transmission areas). The WHO also recommends that tests selected should have false-positive rates of less than 10 percent and invalid rates of less than 5 percent[7].
2. **Stability:** Consider storage and distribution conditions in areas where products are to be used and how the selected tests have performed. Do any reagents or tests need refrigeration? Are there special storage conditions? How long is shelf life in typical conditions?
3. **Ease of use:** Does the testing method consider blood safety risks and try to decrease them? Are instructions easy to follow? Are numbers of steps required to perform the test, or time required for testing and results, limited? Are additional consumables required to use the test? Are items bulky to store or transport?
4. **Price:** What is included in the price, and what is the price per test? Are additional consumables required but not included? Is additional buffer solution needed? Additional storage or distribution costs? Does the test require complex training requirements?
5. **Contents of Kit:** Does the RDT include all components required for testing in one pouch—cassette, lancet, sterile swab, pipette, and buffer? In cases in which a single bottle of solution is meant to be used with multiple tests, the open bottle may degrade at a faster rate, and wastage is likely.

2. Choose RDTs appropriate for the situation in-country and limit switching brands.

As the WHO and partners continue to evaluate the quality of RDTs and as new RDTs come to market, countries may be tempted to change kits they use. In addition to quality, other factors must be considered, such as sensitivity and specificity of the test selected, endemicity of the region where the tests will be used, storage conditions and heat stability of the RDT, packaging, ease of use, consumables required, and price. Additional factors for consideration are programmatic need and lot testing[7]. Remember that changing a test may require (re-)training staff and possibly procuring, distributing, and managing additional supplies. Thus, switching to a different RDT that rates only slightly higher in quality than the RDT currently used may not merit additional efforts and costs.

3. Conduct a lab standardization exercise and include level of use for RDTs and antimalarials in STG.

Standardization is the process of setting test menus, techniques, and SOPs for each level of the health system. For malaria, a standardization exercise can help to determine which levels of the laboratory system and/or regions of the country will use RDTs rather than microscopy for diagnosis. Microscopy may be preferable in areas with low case load and experienced laboratory staff while RDTs may be more appropriate for use by CHWs in remote areas with little access to the laboratory system or areas of high endemicity.

[6] The WHO worked with the Foundation for Innovative New Diagnostics (FIND), the Centers for Disease Control and Prevention (CDC), and the Special Program for Research and Training in Tropical Diseases sponsored by UNICEF, UNDP, World Bank, and WHO (TDR).

[7] WHO. *Information note on recommended selection criteria for procurement of malaria rapid diagnostic tests (RDTs)*. September 16, 2010. http://www.who.int/malaria/diagnosis_treatment/diagnosis/RDT_selection_criteria.pdf

Lab standardization results in a reduced range of tests and equipment and thus increases economies of scale, thereby providing leverage in negotiating procurements. Additionally, having a narrower range of equipment and techniques facilitates training of staff.

As a result of a standardization exercise, STGs may need updating to include specific recommendations for level of use of RDTs, including that by community health workers.

Considerations in Choosing Antimalarials

1. **Guidelines:** Antimalarials selected should be part of national standard treatment guidelines, which should follow the latest version of the WHO *Guidelines for the Treatment of Malaria.*
2. **Formulation and presentation:** Choosing an FDC will decrease pill burden and increase adherence and rational use, but not all FDCs are alike, and guidance regarding cutting and combining presentations (when out of stock) must be developed for each FDC. If an FDC is not available, select co-blistered or co-packaged products. Severe malaria medicines must be in formulations easily administered to a comatose patient. Size of packaging, labeling, and instructions should also be considered. Formulations such as soluble tablets should be available for use in children.
3. **Quality:** Review stability of products in conditions under which antimalarials are to be stored and distributed. Is the product WHO-prequalified or SRA-approved? Does the manufacturer follow good manufacturing practice (GMP)?
4. **Cost:** Consider total cost of treatment and not cost of units when all other considerations are the same.

4. For RDTs, determine how additional consumables required for testing will be resupplied to the testing facility.

One common challenge regarding RDTs is managing reagents and other consumable laboratory supplies such as lancets, pipettes, blood collection devices, and gloves needed for test administration. Almost all of these consumables can be used for a variety of tests and activities in a laboratory. Tracking supplies used only in malaria testing separately from those used for other purposes would demand more time from service providers, create more room for error, and not provide significant program benefits.

If an established supply chain for laboratory consumables is in place, system designers should allow that system to ensure supplies needed for testing. If none exists, such products could be included in the LMIS for RDTs to ensure availability for testing. The system designer should recognize that commodities other than just RDTs are needed for administering a test and then explore and document different options for the ensuring that these products are available at the SDP level, and determine which system makes the most sense.

Please see the *Handbook for Managing Laboratory Supplies* (USAID | DELIVER Project, 2008) for a more complete description.

5. Choose products that are fixed-dose-combinations (FDCs).

Several WHO-prequalified manufacturers make FDC AL, and an AS/AQ FDC formulation is available. Not only are FDCs easier to manage logistically, but they also improve health outcomes by increasing adherence and therefore decreasing risk of resistance. Single tablets reinforce the understanding that ACTs are one medicine and thus promote rational use of medicines.

While procuring co-blistered AS + AQ is possible, this is becoming less common. Some patients had been taking only one tablet in the co-blister, reducing effectiveness of treatment and promoting resistance. Therefore, programs should use single FDC tablets when possible.

6. Limit first-line treatment options.

Limiting first-line treatment of uncomplicated malaria to one ACT will ease all functions of the logistics cycle, as noted in the chapter introduction. Some national malaria control programs may want more than one option due to fear that one option may not be available in the marketplace or to have flexibility to switch options when one advances in formulation (longer shelf life or new FDC). The relative ease in managing one ACT in the supply chain should be weighed against potential risk of increasing chances of resistance, although no evidence exists of increased resistance when limiting ACTs to one option for first-line treatment.

When two options are given for first-line treatment of malaria, typically the second ACT displays little movement, leading to expiries.

7. If procuring for public and private sectors, choose products with packaging that differentiates the two.

For governments that may be procuring for the public and private sector (e.g., as part of a public-private partnership), selecting products with packaging visually distinguishable for use in one sector or the other may be a good idea. This may help to identify diversion/pilfering of high-value ACTs and RDTs. Such packaging distinctions are available in the marketplace for ACTs. For example, Sanofi-Aventis markets AS/AQ FDC for the private sector under the brand name Coarsucam® and ArteSunate-AmodiaQuine Winthrop® for the public sector, although they are the same medication. Use of RDTs has been limited predominantly to the public sector, but as they become more widely available in the private sector, such procurement specifications should be considered.

Resources

Foundation for Innovative New Diagnostics (FIND) web-based interactive guide to inform RDT selection on the basis of target malaria species, minimum detection rate for *P. falciparum* and *P. vivax* at 200 parasites/µl, invalid rates and test format.
http://www.finddiagnostics.org/programs/malaria/find_activities/product_testing/malaria-rdt-product-testing

Information note on recommended selection criteria for procurement of malaria rapid diagnostic tests (RDTs), WHO, September 2010
http://www.who.int/malaria/diagnosis_treatment/diagnosis/RDT_selection_criteria.pdf

Information note on interim selection criteria for procurement of malaria rapid diagnostic tests (RDTs), WHO, January 20, 2010
http://new.paho.org/hq/index.php?option=com_docman&task=doc_details&gid=5909&Itemid=99999999

Laboratory Standardization: Lessons Learned and Practical Approaches
http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/LabStand.pdf

Malaria Diagnosis: A Guide for Selecting Rapid Diagnostic Test (RDT) Kits – 1st edition, UNICEF, October 2007
http://www.unicef.org/supply/files/Guidance_for_malaria_rapid_tests.pdf

Malaria Epidemics: Forecasting, Prevention, Early Detection and Control, WHO, December 2003
http://www.searo.who.int/LinkFiles/Malaria_MalariaERBM2004.pdf

WHO Guidelines for the Treatment of Malaria, Second Edition
http://www.who.int/malaria/publications/atoz/9789241547925/en/index.html

WHO Malaria Rapid Diagnostic Tests Evaluation Programme
http://www.wpro.who.int/sites/rdt/who_rdt_evaluation/

Quantification

Purpose

After selection, each product must be quantified. The purpose is to estimate quantities and costs of products required for a specific health program or service and to determine when the products should be procured and distributed to ensure an uninterrupted supply. Results of quantification can be used to help maximize available resources for procurement, advocate for mobilization of additional resources when needed, and inform manufacturer production cycles and supplier shipment schedules.

The Quantification Process

For antimalarial products, a quantification exercise follows the same key steps as for other types of products that a program distributes. These steps, outlined in figure 2 below, include preparation, forecasting, and supply planning.

Quantification is a process of continuous monitoring and regular updating of quantification results. Data inputs and assumptions should be updated to incorporate changes in program policies and plans that will affect demand for products.

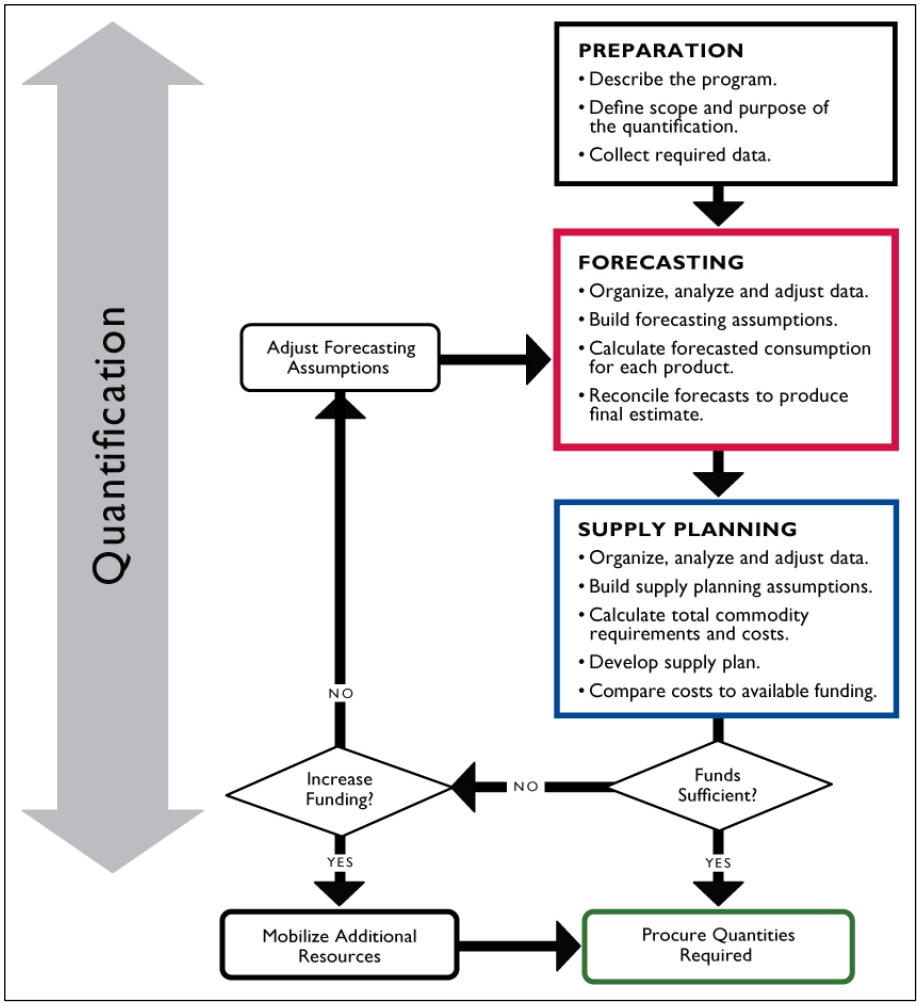
This chapter describes recommendations for quantification of antimalarial medicines, which should consider use of ACT formulations as a first-line treatment, treatment of severe vs. uncomplicated malaria, prevention of malaria in pregnant women, and variations in country guidelines to accommodate provision of pre-referral treatment and second-line treatment.

Forecasting Methods

Essentially, three types of data can be used for forecasting—consumption, services, and demographic/morbidity.

- **Consumption data** are historical data on actual quantities of products dispensed to users or used to provide a specific service during a specified period. For malaria products, examples include consumption of 50,000 AL 1x6 blister packs over six months and use of 45,000 RDTs over 12 months. Historical consumption trends are analyzed and used to estimate quantities of each product that will be dispensed or consumed during each year of quantification.
- **Services data** include historical data on number of services provided and of client visits, patients seen, episodes treated, or tests conducted over a specified period. Like consumption data, these are facility-based. For malaria products, examples include number of episodes of malaria treated (disaggregated by uncomplicated vs. severe), number of malaria patients, or number of patients tested. Historical services data are analyzed and used to estimate number of patients, episodes, or tests conducted. These data must then be converted into products—for example, using STGs—to produce a forecast consumption of specific products.

Figure 2. Steps in Quantification



- **Demographic data** include data on the number and characteristics of the population targeted for services, i.e., age breakdowns. **Morbidity data** are data on prevalence or incidence of a disease present in a population in a given year or at a specific time. For malaria products, examples include population size and growth rate, age breakdowns, and incidence and prevalence of malaria or types of malaria. Like a forecast based on services data, these data are used to estimate number of patients, episodes, or tests conducted. These data must then be converted into products to produce a forecast consumption of specific products. Unlike services or consumption data, these are not routinely available historical, facility-based data but rather population-level and usually available through special surveys.

With any data types, assumptions must be made about factors expected to influence demand for individual products during the quantification period.

Length of Forecasts

Since ACT use may be unpredictable due to roll-out of prevention campaigns and policy changes regarding diagnosis before treatment, short-term (two-year) forecasts with one-year procurement

planning are recommended. Forecasts should be reviewed and updated every three months to compare the *projected* number of episodes to be treated with the *actual* number and to compare the *forecast* and *actual* consumption of products.

Accuracy and validity of antimalarial medicines forecasts is subject to evolving developments in clinical practice due to a shift in treatment guidelines, diagnosis policies and prevention campaigns. Nonetheless, programs should be encouraged to conduct forecasts beyond one year to estimate future requirements and funding needs.

Characteristics of Antimalarials Relevant to Quantification

Certain characteristics of antimalarials, including dosage and administration requirements, should be factored into quantification.

- *Treatment:* Antimalarial treatment may consist of a single medicine (e.g., quinine) or a combination of two (e.g., artesunate + amodiaquine).
- *Formulation:* Antimalarials may be prescribed in separate tablets or in an FDC (co-formulated), syrup, intramuscular injection, intravenous infusion, or rectal suppository.
- *Prescription:* Recommended dosages for antimalarial treatment are determined mostly by patient weight and age.

You may need to perform conversions to account for these characteristics. As always with quantification, be sure to document assumptions and explain calculations.

Further details on commonly used antimalarial medicines are provided in Appendix A and further information on forecasting for malaria programs is provided in Appendix B.

Recommendations

The following recommendations consider special characteristics of malaria products. For more information about quantification in general, please see *The Logistics Handbook* and other references at the end of this chapter.

1. Allow ample preparation time.

Quantification for antimalarials, as for other types of products, requires preparation. However, because of general lack of data, preparation for an antimalarial medicines quantification is particularly important, before and on arrival in-country. In particular, allow time for—

- *Collecting data:* Collect whatever is available (logistics, services, demographic, STGs, etc.) and be sure to compare data from different sources to determine realistic numbers and obtain a realistic picture of the operating environment.
- *Visiting sites:* Although you may not be able to collect data at sites (i.e., it may be difficult to access from registers), site visits are very useful to help understand actual diagnostic and treatment practices. You must determine a sampling methodology or whether you will simply visit two easily accessible facilities.
- *Determining assumptions:* At the beginning of the activity, gather a diverse and comprehensive group of stakeholders, including those involved with logistics, treatment, and vector control. These key people must participate in discussions to develop consensus around the assumptions.

2. Define the scope of the malaria program.

To determine which products will be included in the quantification, describe the scope and range of interventions being provided by the malaria program—for instance, pre-referral treatment, treatment of adults and children, prevention of malaria in pregnancy, treatment of severe malaria, or use of RDTs before administering ACTs for treatment of fever. It is important to know geographic and population targets to help determine quantities and types of products required for the program.

Furthermore, establish whether products for the private sector will be included in the quantification or cover just the public sector. You must understand the private sector role and what treatments clients tend to access at private facilities because this will affect your forecast quantities for the public sector.

Many countries do not have reliable consumption data for malaria products because efforts to strengthen logistics systems may be relatively recent. HMIS systems are similarly hindered. Without consumption data, countries must establish reasonable estimates of fever episodes and reported malaria cases. Be sure to collect data from multiple sources (e.g., national programmatic data, HMIS, surveillance) for comparison. Do not rely on one source of data.

Because presentation and treatment have many variations (e.g., severe vs. non-severe, weight bands, packaging), you must be especially clear and consistent when gathering data for quantification of antimalarials. For ACTs, when collecting data on dispensing by pack size, you may also want to try collecting information about patient weight and age to help estimate required presentations to treat various types of clients, including adults, children, and pregnant women.

Information can be gathered from services data at the facility and central levels, the HMIS, or the LMIS, if there is one. Consider possible regional variations in the above data. See Appendix B for information on what type of data to gather and on proxy data.

If the program has experienced stockouts, past consumption data will underestimate what consumption would have been had products been continuously available at all facilities. You must make adjustments to cover stockout periods as for other products.

Country Example: Determining Numbers of Malaria Cases in Nigeria

In the absence of consumption data ,and inconsistent and incomplete demographic and morbidity data in Nigeria, the quantification team developed two forecast scenarios from available data. In the first, the estimated mean number of annual fever episodes was calculated. This number was adjusted to account for the impact of various interventions such as the LLIN campaign, IRS, and increased use of RDTs. In the second, the projected number of annual malaria cases per person was calculated and adjusted to reflect how many fever episodes that would represent because all fevers are treated as malaria in Nigeria. This scenario also accounted for impact of interventions. Because no data existed to discount use of either scenario, the team took the median of the two as the final forecast estimate.

3. Use the smallest packaging unit when quantifying.

Pack size is the number of treatments of the medicine per unit of supplier packaging. The smallest ACT packaging unit is a single blister pack—one treatment that may come in a pack of 25 blister packs/box or 10 blister packs/box, depending on the supplier. Therefore, quantify by blister, not tablet. However, for some other antimalarials, such as quinine, quantify by tablet.

If you can examine consumption data, it is important to understand how it reflects actual dispensing at the facility level because some providers may break or combine blisters if they run out of a particular presentation (i.e., 1x6).

At time of procurement, the ordered quantity must be rounded up to the nearest whole unit of supplier packaging.

4. Be aware that STGs may not reflect actual service provider practice.

When gathering information for antimalarial medicine quantification, review national malaria standard treatment guidelines, national malaria policy and program planning documents, program evaluation and progress reports, and other recent service delivery or logistics system assessment reports that are available. However, there is often a discrepancy between STGs and actual dispensing practices. So try to conduct site visits to observe whether providers are adhering to STGs. Also review supervisory reports if they document STG adherence. In particular, try to determine whether and to what extent service providers are:

- Prescribing antimalarials based on fever rather than results of RDTs/microscopy
- Treating patients according to the national algorithm for management of malaria at different levels of health care
- Cutting or combining ACT blister packs

5. Account for seasonality in forecasting and supply planning for ACTs and RDTs.

Since demand can fluctuate throughout the year for some settings, identify months in which demand is expected to rise (i.e., the rainy season) or drop. One option to account for projected spikes and dips in consumption in your forecast is to estimate a percentage change in monthly consumption from consumption data and/or case data over a calendar year. An example is below.

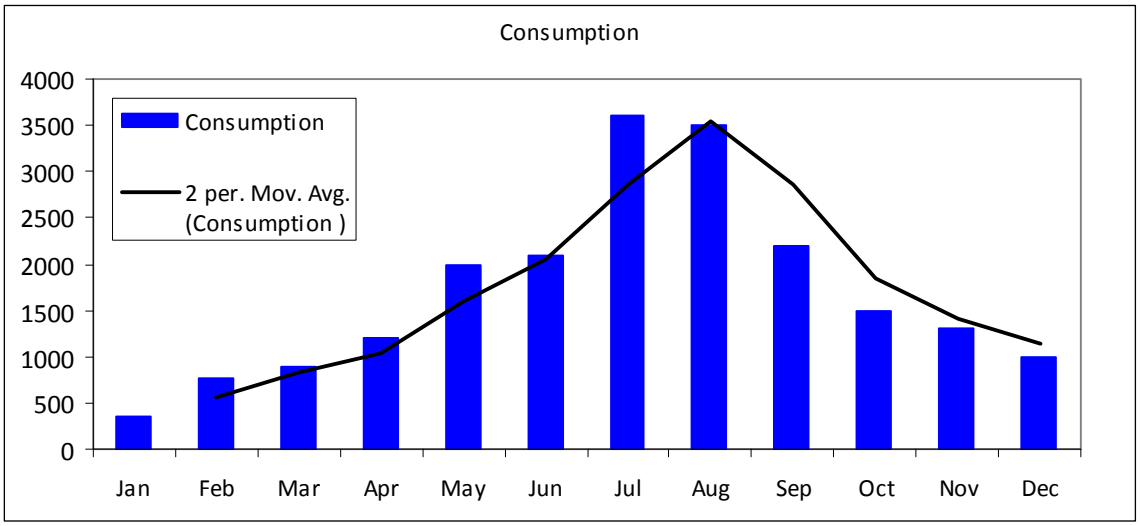
Table 2. Percentage Change in Monthly Consumption

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Consumption	360	760	890	1200	2000	2100	3600	3500	2200	1500	1300	1000
Percentage change from previous month		211%	117%	135%	167%	105%	171%	97%	63%	68%	87%	77%

The percentage change can then be used for future forecast and supply planning.

Another way to view the above information is by a bar graph and a moving average trend line (figure 3). This may also be useful in forecasting and supply planning.

Figure 3. Bar Graph of Consumption Data with Trend Line



Supplies must arrive at facilities before the anticipated spike in demand, and lead time must allow for products to move from the central level to SDPs. If certain facilities become inaccessible during the rainy season, considering this while supply planning may help to ensure that required supplies arrive before the rain. PipeLine, a software tool for supply planning developed by the USAID | DELIVER PROJECT, now has a function to assist with seasonality. During the rainy season, you may want to establish a temporary distribution point at which you can pre-position stocks and then resupply hard-to-reach facilities from there rather than the central or regional level as discussed in the ICS chapter (recommendation 5).

6. Quantify by geographic regions, based on endemicity.

In countries where certain areas are endemic while others are not, you may want to quantify by region, if data are available, since incidence will not be evenly distributed countrywide. If regional data are unavailable, find out what percentage of the population lives in endemic areas and extrapolate population numbers to develop a disease map for the country. You may also want to consider the percentage of the population living in urban vs. rural areas if malaria endemicity varies in those areas.

7. Refer to lab registers to capture number of people tested and results.

Another important data source for quantification are lab registers that document numbers of people tested and the positive or negative results of each test. Use this information to determine numbers of RDTs consumed and numbers of reported malaria cases. Technicians rather than clinicians perform lab tests, and lab registers are often kept in a different area from patient treatment records or stockcards. So they may be a useful point of comparison with services or logistics data as discussed in the LMIS chapter (recommendations 6 and 8).

8. Adjust forecast consumption of antimalarial medicines to account for planned prevention interventions.

When estimating numbers of malaria episodes to be treated in different population groups, consider planned or ongoing interventions (e.g., LLIN utilization, IRS coverage) and use of parasitological

confirmation by microscopy or RDTs that may affect numbers of episodes treated. Multiple control measures are usually scaled up at the same time, and the impact of concurrent interventions (ACTs, LLINs, IRS) is difficult to quantify. Thus, you must work with different stakeholders and obtain their input on target achievements and how that will impact incidence of malaria. Refer to Appendix B for references.

9. Identify other areas for malaria logistics system strengthening during the quantification exercise.

The quantification process offers an opportunity to identify areas of weakness and advocate interventions for system improvements. Although this advocacy is outside of the quantification process, it impacts successful future quantifications. Developing and maintaining a robust LMIS and developing commodity security strategy to ensure long-term financing is critical to making certain that the overall supply chain can be strengthened and that quantification can become increasingly effective and institutionalized over time.

Resources

Manual for Quantification of Malaria Products: Artemisinin-Based Combination Treatments, Rapid Diagnostic Tests, and Long-Lasting Insecticide Nets. MSH/SPS. December 2010.

Quantification of Health Products: A Guide to Forecasting and Supply Planning for Procurement. USAID | DELIVER PROJECT, Task Order 1. 2008. Arlington, VA: USAID | DELIVER PROJECT, TASK Order 1. http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/QuantHealthComm.pdf

*World Malaria Report 2008, Annex 1: Estimating the numbers of malaria cases and deaths by country in 2006.*World Health Organization, http://www.searo.who.int/LinkFiles/Reports_WMR_2008_Final.pdf

Procurement

Purpose

Product procurement is an important activity in ensuring that correct products are available in-country and ready for distribution when needed. The procurement unit also ensures that national procurement regulations and procedures are properly implemented.

The Procurement Process

After a supply plan has been developed as part of the quantification process, quantities of products must be procured. Health systems or programs may procure from international, regional, or local sources of supply, or may use a procurement agent. In any case, procurement should follow specific procedures that ensure an open and transparent process.

Appendix C provides a checklist that describes key steps in procuring quality antimalarial medicines. While the steps are listed sequentially, in practice they do not necessarily occur consecutively, nor must all steps be repeated for each tender.

Specifications

The procurement unit must ensure that, in addition to product information provided by program managers (i.e., generic name, dosage, formulation, and unit packaging requirements), suppliers produce products that meet regulatory and shipping/packaging requirements, These must include proof that products are manufactured at facilities that meet good manufacturing practices (GMP) certification requirements or have WHO prequalification status and can provide products meeting certain technical specifications. These include standards for raw materials and requirements for shelf life, labeling, language, and inner and outer packaging.

Technical specifications also include testing requirements for quality assurance, and packaging and shipping requirements. The specifications are the primary way that countries protect populations against counterfeit or substandard products and ensure that products delivered are properly labeled and adequately protected from heat and cold during shipping.

Clear specifications about formulation and packaging are especially critical for antimalarials since there are multiple presentations of ACTs and different types of RDTs.

General Considerations

In summary, key considerations about the procurement process include:

- Good product specifications are critical to good procurement
- Procured products should meet all program requirements and quality standards
- Persons familiar with logistics considerations and technical specifications of products (i.e., pharmacists for ACTs and laboratory staff for RDTs) should be involved

- Aligning procurement cycles with availability of financing will help to ensure that availability of funding does not delay procurement
- Procurement is often lengthy, and the full timeline must be known and communicated with other stakeholders
- Managing the bidding process is critical to ensure that procedures are followed and the process is well documented
- While lowest cost is important to selecting a supplier, other important criteria include quality of products, ability to meet delivery schedule. and past performance.

Recommendations

The following recommendations consider special characteristics of malaria products. For more information about procurement in general, please see *The Logistics Handbook*.

1. Plan procurements to factor in lead time and date needed in-country.

Procurement can be lengthy, and as a good rule of thumb for the procurement cycle, it should be initiated at least six to nine months before products are to arrive in-country, although this can differ by product and/or country. Procurement plans should be made on a 12-month, rolling basis. Although production lead times vary with product and brand, ACTs can require 12 weeks of production lead time, other antimalarials can require 20 weeks, and RDTs can require four to eight weeks—plus time for quality assurance (QA) testing, transport from the manufacturer, customs clearance, and in-country distribution.

Once funding is available, the procurement process can be initiated. Even if product does not need to arrive in country for a while, place the order in advance to be sure that it is available when needed. It is possible to stagger large, bulky orders that require considerable storage space. In addition, procurement contracts should be negotiated to allow flexibility to make call-downs of products when needed, accommodate changes in consumption, and ensure an interrupted supply at the national level.

Product shipments should be planned to ensure that antimalarials arrive before malaria season and that RDTs are in-country in time for testing campaigns.

Furthermore, be sure that required training and/or preparation for product use is complete before products arrive in-country. Otherwise, products may sit in storage for significant periods of time, using shelf life and increasing exposure to heat, moisture, and pilferage.

2. Procure only quality-assured products.

PMI/USAID will allow procurement only of USFDA (or equivalent)-approved ACT and in the absence of an SRA-approved ACT, a WHO-prequalified ACT. Therefore, programs can buy only two ACTs and FDCs with USAID funds—Novartis's Coartem and Sanofi-Aventis's FDC AS/AQ. Other donors, including GFATM and (WB, have their own quality requirements.

Quality Assurance SOPs

USAID | DELIVER PROJECT follows strict quality assurance SOPs. Products require a quality evaluation for every batch. This includes pre-shipment sampling and testing for all products that are not USFDA/SRA-approved and that include LLINs, RDTs, medicines used for treatment of severe malaria, and some ACTs.

Other antimalarials such as SP and quinine tend to be generic and relatively inexpensive, usually manufactured in India. There is no WHO-prequalified manufacturer of these products.

Except for Coartem, which is USFDA-approved, the USAID | DELIVER PROJECT conducts QA testing of all products at the manufacturer, pre-shipment, using WHO pre-certified labs. As mentioned above, time to undertake these quality assurance requirements should be factored into procurement lead time.

Country Example

A West African country decided to procure severe malaria kits for pregnant women and children under five. The pregnant women and child kits comprised quinine ampoules (women's kit only), dextrose 5 percent, dextrose 10 percent, paracetamol ampoules, an infusion giving set, needles, syringes, a Foley catheter, and adhesive plaster.

Due to procurement of the paracetamol ampoules for injection, which required a special waiver from the founding agency, and a long production and QA process, the lead time increased from 8 to 10 to 14 months. The paracetamol ampoules represented a small percentage of the shipment's total value but caused substantial delay for the rest. The original estimated time of arrival changed from September 2010 to mid-February 2011.

For RDTs, at least seven branded manufacturers are included in the WHO RDT product testing report.[8] Programs can choose RDTs produced by any of these manufacturers. In general, because most countries have standardized testing protocols and personnel trained to administer a particular type of test, they should consistently procure the same type of RDT.

3. Avoid country-specific markings on packaging.

Some programs like to request special markings in product specifications (e.g., *Government of X – Not for Resale)*. While some believe that such markings can reduce theft or pilferage, it's not clear that they do. Adding special markings increases production lead time and cost. Furthermore, for branded products such as Coartem, packaging involves regulatory issues, and any changes to it would require additional registration and approvals, again increasing lead time and cost. This is because USFDA approval includes packaging review. Furthermore, boxes of some product such as RDTs are already text heavy and have no physical space for additional markings.

Most products come with multilingual inserts, and administration directions tend to be pictorial, reducing the need for translation or literacy.

4. Consider supply chain challenges when determining whether to procure products as kits.

Certain products in malaria management are available as kits (i.e., those for treatment of severe malaria or microscopy). Several challenges arise with selecting and procuring these items as kits—procurement lead time is based on availability of the product in the kit with the longest lead time; the kits' shelf life is based on the item inside with the shortest shelf life; kits typically cost more when compared to buying individual items separately; difficulty determining units of resupply to facilities; and the rate of use varies for individual components with some items exhausted before others, creating great wastage.

[8] http://www.wpro.who.int/sites/rdt/who_rdt_evaluation/

Resources

Information note on recommended selection criteria for procurement of malaria rapid diagnostic tests (RDTs). WHO, September 2010. http://www.who.int/malaria/diagnosis_treatment/diagnosis/RDT_selection_criteria.pdf

Roll Back Malaria Commodity Services: A unit of the RBM Secretariat working together with partners to support the procurement and supply management efforts for medicines and diagnostics (as well as nets and insecticides). http://www.rbm.who.int/psm/index.html

WHO Malaria Rapid Diagnostic Tests Evaluation Programme: http://www.wpro.who.int/sites/rdt/who_rdt_evaluation/

WHO Global Malaria Programme: Good Procurement Practices for Artemisinin-based Antimalarial Medicines. WHO, 2010. http://whqlibdoc.who.int/publications/2010/9789241598927_eng.pdf

Storage and Distribution

Purpose

The purpose of a storage and distribution system is to ensure physical integrity and safety of products and their packaging as they move from the central storage facility to SDPs and to clients. A sound system will preserve quality of products, ensuring that they reach the client in usable condition with minimal loss or waste. For malaria products, this entails protecting products from excessive heat, direct sunlight, moisture and water, pests, pilferage, and expiry.

Acceptable warehouses and storage rooms are clean and secure, and adequate distribution systems have dependable and secure delivery vehicles. The in-country pipeline should be as short as possible, of particular importance for malaria products with short shelf lives. Fewer levels in a system means fewer storage points. Limiting the number of times products are transported reduces opportunities for damage and diversion. Fewer people handle the products, which can help to increase accountability and minimize loss, damage, and pilferage, which is relevant for relatively high-value malaria products.

These products should be stored according to standard guidelines. Like all health products, they require procedures for safe storage that maximize shelf life and make them readily available for distribution. Well-functioning warehouses and storerooms at various levels will have sufficient space, acceptable storage conditions, explicit QA mechanisms, adequate product security, and standard storage procedures.

Health products, including those for malaria, can usually be distributed via a pickup system, in which the lower level collects products at the supplying facility, or a delivery system, in which the upper-level supplying facility brings products to the lower-level receiving facility. Regardless of type of distribution mechanism, transportation must be available whenever needed to fill regular or emergency orders. This is particularly important when vehicles are shared for multiple purposes such as product delivery and supervisory visits.

Recommendations

The following recommendations consider special characteristics of malaria products. For more information about storage and distribution in general, please see *The Logistics Handbook*.

1. Allocate sufficient storage space for products.

Due to bulky packaging, ACTs and RDTs may require more storage space than other essential medicines. Therefore, when integrating malaria products into an existing supply chain, designing a new system to support a malaria program, or expanding their use by community health workers, assess existing storage space at all system levels and determine whether there will be enough room. Consider storage space capacity in designing an ICS, and adjust stock levels to accommodate existing capacity or recommendations to expand current capacity (see the ICS chapter). If you anticipate space constraints, discuss with the government and partners options for renting or constructing additional storage facilities, and/or installing racking, as appropriate. Furthermore,

consider staggered, more frequent delivery of large purchases, and reduce resupply periods internally. The review period must still be longer than the lead time.

2. Maintain cool chain for products, as required.

To ensure quality and full length of shelf life, ACTs require storage at room temperature (15°C-25°C), while some RDTs and suppositories require cool storage (2°C-30°C). RDTs should be kept in the coolest part of a health facility but do not need refrigeration and should never be frozen.

In general, products should be kept under controlled temperatures in centralized storage, and long-term storage in peripheral facilities with no temperature control should be avoided, if possible. In locations where air conditioning is unavailable, simple measures can keep temperatures low. To protect products from sunlight, shade windows. To provide ventilation, open windows or install louvered windows and/or ceiling fans. To prevent high-ceiling temperatures, use a reflective roof surface and install a ventilation turbine and/or eave vents.

Throughout distribution, direct sun exposure should be avoided, and transport should be coordinated to minimize exposure to temperatures exceeding the manufacturer's recommendation.

3. Adhere to first-to-expire, first-out (FEFO) procedures.

Use products first that will expire first. Remember that most recently delivered products may expire sooner than previously delivered ones, so you may need to reorganize stocks. Do not use products after expiry because quality cannot be assured since expired RDTs may not result in reliable tests, and ACTs may not be efficacious and could lead to resistance.

4. Establish policy and procedures to manage short-dated stock.

Since some malaria products have a relatively short shelf life, stock may be short-dated by the time it arrives at a region or SDP. Therefore, it is important to create a national policy for addressing short-dated stock and to train staff at different levels on appropriate procedures. Establish a policy that facilitates stock transfers between facilities or regions, or even between countries, if necessary. Be sure all documentation is thorough and clearly disseminated.

5. Provide appropriate security during storage and distribution.

Some malaria products such as ACTs and RDTs are significantly high value relative to most essential medicines managed through supply chains and thus potentially more susceptible to pilferage. During storage and distribution of these products, implement security protocols such as barring windows, padlocking doors, and never leaving products unattended. Strengthened ICSs and LMISs also enhance product security by increasing their transparencies and visibility.

6. Establish policies and procedures for waste management and disposal.

Expired or damaged products, whether antimalarials or RDTs, must be disposed of properly. RDTs generate *infectious* waste, such as sharps and blood collection devices, and *non-infectious* general waste, such as packaging (envelope), buffer and carton boxes. These types of waste should be handled and disposed of separately.

If national guidelines and policies for waste management are available, adhere to them. In general, segregate infectious waste and keep sharps (i.e., lancets, needles, and blades) in a sharps box, separate from non-sharps (i.e., used cassettes, blood transfer devices, contaminated gloves, etc.). Store infectious waste in a distinct, clearly marked area until disposal. Appropriate disposal of

infectious waste will depend on local conditions and regulations but can include burial and incineration.

Resources

Management of Solid Health-Care Waste at Primary Health-Care Centres: A Decision-Making Guide. WHO.
http://www.who.int/water_sanitation_health/medicalwaste/decisionmguide_rev_oct06.pdf

Transporting, Storing, and Handling Malaria Rapid Diagnostic in Health Clinics. USAID | DELIVER PROJECT, 2009.
http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/TranStorRDT_Clinic.pdf

WHO website on Healthcare Waste Management (HCWM)
http://www.healthcarewaste.org/en/650_tech_small.html

Quality Monitoring

Introduction

Understanding the role of quality monitoring in ensuring an efficient and effective logistics system is important. In the logistics cycle, "quality monitoring" appears between each activity of the cycle. The phrase refers to the quality of the *product*, and to the quality of work in the *process*.

QA is specifically focused on the product. The purpose of a QA system in public health pharmaceutical supply systems is to make certain that each medicine or medical consumable reaching a patient is safe, effective, and of standard quality. A comprehensive QA program also spans the entire logistics cycle.

The quality of ACTs is especially important because use of ineffective or unsafe substandard products in malaria treatment may harm individual patients and the community. If parasites are exposed to low levels of antimalarial medicines in the blood, resistant parasites will survive and multiply, potentially leading to emergence and spread of resistant strains.

Therefore, QA is a critical part of the procurement process. Safe and effective medicines must be selected, and each batch must be quality-assured, from starting materials through manufacture and distribution to dispensing.

In terms of RDTs, good-quality diagnostic materials are also important since the wrong diagnosis can lead to treatments for false positives and no treatments for false negatives. That affects forecasting for antimalarial medicines, resulting in under- or overstocking, expired stock, and wasted funds.

Branded and generic products may be counterfeited. Artemisinin-based products are likely targets because they are widely used in countries where regulatory controls tend to be weak and because they are distributed globally through various hard-to-control channels. The large quantities of these relatively expensive products increases potential profits of counterfeiters.

Recommendations

The following recommendations consider the special characteristics of malaria products. For more information about quality monitoring in general, please see *The Logistics Handbook*.

1. **Conduct post-marketing surveillance for RDTs by lot testing after purchase and before use at SDPs.**

Properly used, malaria RDTs can provide a timely, reliable diagnosis at all levels of the health system. However, test performance has varied by lot for some products, possibly due to poor manufacturing or exposure to heat and humidity during transport and storage. Lot variability may have led health workers, users, and regulators to mistrust RDT results. For RDTs to be effective, reliability of test results must be ensured and demonstrated. This not only includes appropriate planning of introduction and enrollment of RDTs but also training and monitoring correct use.

To ensure quality of RDTs when they are received in-country, check all production lots for quality through lot testing before use at facilities.[9] The WHO and the FIND can facilitate the testing. See resources listed at the end of this chapter.

2. Monitor RDT performance at the SDP.

In addition to lot testing before field use, monitoring RDT performance should be put in place. Field monitoring of RDTs can be difficult since it involves comparisons to field microscopy, which has inherent problems. The WHO and its partners recommend two procedures:

- Compare RDT results with expert light microscopy. RDTs and blood films should be taken from the same patients in selected health facilities where RDTs have been appropriately stored and distributed.
- Use expert microscopy at "sentinel" sites or at the central/regional reference laboratory to monitor therapeutic efficacy of antimalarial medicines. Be sure to select highly competent microscopists for evaluation of RDT performance.[1]

Development of recombinant panels is anticipated in 2012 and would allow decentralized lot testing in the field, which would increase monitoring of RDT quality.

3. Visually inspect products at all levels of the health system.

Visual inspection is the process of examining products and their packaging by eye to spot obvious problems with product quality. In a perfect pipeline, all products are stored under ideal temperature and humidity conditions and according to proper storage guidelines. In reality, the quality of storage conditions may vary widely from place to place. In a warehouse facility, storekeepers can best verify quality by regularly checking the condition of all products visually, but users and dispensers may also conduct visual inspections.

Products suffer two basic types of damage during shipping and storage that affect quality: mechanical and chemical. Mechanical damage is caused by physical stresses, such as crushing or tearing when loading, offloading, or stacking cartons or inner boxes. Such damage is usually limited to crushed or torn parts. Chemical damage is more difficult to detect and usually not obvious during visual inspection. Laboratory testing is often required. Some indications of chemical damage may include changes in product color, odor, or consistency.

For each RDT lot received, for example, check the quantity and expiry date and see that all original boxes are unopened and in good condition. You may want to open a few kit boxes to ensure that the test envelope is intact. Check that bottles of buffer are full, but be sure not to inadvertently unseal childproof lids—which may seem loose at first glance—since this can lead to wastage if the buffer is not used promptly. For ACTs, check for crushed or powdered tablets in blister packs.

For greater detail on common quality problems and recommended actions, please see the *Logistics Handbook* or *Transporting, Storing, and Handling Malaria Rapid Diagnostic Tests in Health Clinics*.

4. Ensure that policies and procedures exist at the national level for product recalls.

Policies and procedures should be in place for prompt and effective recall of malaria products known or suspected to be of poor quality. Recording batch numbers of products would ease

[9] http://www.wpro.who.int/NR/rdonlyres/9F42AF75-AC81-48E5-AAA2-0FB9B630425C/0/RBMGFATMRDTApr17Fin2.pdf

tracking of affected products if a recall is necessary. Some donors are also requesting tracking to lower levels by batch number and recalls in response to pilferage. Greater automation would simplify this tracking.

Resources

Managing Drug Supply (MSH and WHO, 1997). Chapter 18, Quality Assurance for Drug Procurement.

Rapid Diagnostic Tests in Malaria Case Management: Planning, Procuring and Implementing: Suggestions for Incorporation of Malaria RDT-based Diagnosis into Proposals to the Global Fund. FIND, TDR and WHO Global Malaria Program. April 2009. http://www.wpro.who.int/NR/rdonlyres/9F42AF75-AC81-48E5-AAA2-0FB9B630425C/0/RBMGFATMRDTApr17Fin2.pdf

Transporting, Storing, and Handling Malaria Rapid Diagnostic Tests in Health Clinics. World Health Organization-Western Pacific Regional Office (WHO-WPRO), USAID | DELIVER PROJECT, Foundation for Innovative New Diagnostics (FIND), Roll Back Malaria Partnership, President's Malaria Initiative (PMI), and UNICEF. July 2009. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 3; and Manila: WHO-WPRO. http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/TranStorRDT_Clinic.pdf

Monitoring and Supervision

Purpose

Routine monitoring, supervision, and periodic evaluation of logistics system activities help to demonstrate how well the system performs, areas that can be improved, and the system's impact on service provision. Collecting monitoring and evaluation (M&E) data allows program managers to provide feedback to staff and improve system performance, to report results to stakeholders, and to justify the need for additional resources when appropriate. One of the most important reasons to do M&E is to improve program management and ultimately logistics system performance.

Monitoring: Ongoing and routine collection and analysis of measurements or indicators to determine progress toward objectives.

Evaluation: Periodic comparison of objectives with accomplishments and how the objectives were achieved, involving a more formal and structured system assessment.

M&E plans should have clearly defined goals and supporting objectives. An example of a typical goal for a malaria program is to reduce malaria morbidity and mortality until the disease is no longer a public health problem in the country. Specific objectives in support of this goal could include[10]:

- To provide early diagnosis and prompt treatment with effective medicines to 90 percent of malaria patients
- To provide effective malaria prevention to 100 percent of population at risk
- To provide pre-referral treatment and timely referral of 90 percent of severe malaria cases to the hospital
- To strengthen malaria epidemiological surveillance system
- To strengthen program management capacity, M&E, and procurement and supply management (PSM)

Draft an M&E plan for the malaria supply chain to correspond to the National Malaria Strategic Plan (NMSP). It should contain goals and targets that consider the concerted efforts of country programs, donors, and partners to scale up efforts to prevent and treat malaria. It should be informed by standards and recommendations from global consensus groups such as the Roll Back Malaria Monitoring and Evaluation Reference Group (RBM-MERG)[11].

Dedicated staff must be available and committed to supervision, monitoring, and evaluation. Implementation of a logistics management unit (LMU) can greatly increase monitoring, evaluation and supervision of malaria supply chains. An LMU is a management structure responsible for

[10] Government of the People's Republic of Bangladesh National Malaria Control Program http://www.nmcp.info/index.php?option=com_content&view=article&id=39:front-page

[11] For more information on overall M&E recommendations for malaria programs, including a list of recommended indicators, see "Framework for Monitoring Progress & Evaluating Outcomes and Impact," Roll Back Malaria, 2000.

organizing, monitoring, and supporting all supply chain activities within the logistics system. The LMU identifies supply chain problems, develops interventions to address them, and implements those interventions. An LMU may be responsible for logistics data management, quantification, M&E, supervision, system design, implementation and training, and coordination and collaboration.

To learn more about LMUs, please see *Logistics Management Units: What, Why, and How of the Central Coordination of Supply Chain Management* available at http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/LogiManaUnits_Guide.pdf.

Recent increases in funding for malaria control are expected to significantly reduce malaria incidence and prevalence. As such, logistics data should be compared to health, patient, and disease data to improve understanding of linkages between product availability and malaria rates, and to better inform program officials about outbreaks as malaria moves from an endemic to epidemic disease in some places.

An M&E program must have clearly defined indicators and methods for collecting necessary data and should also establish supervisory roles and responsibilities for malaria program staff at all supply chain levels. Recommendations listed below are malaria-specific and do not constitute a full M&E approach. For more information on developing an M&E plan for a logistics system, please see the "Monitoring and Evaluating Supply Chains" chapter of the Logistics Handbook.

Recommendations

The following recommendations consider special characteristics of malaria products. For more information about monitoring and evaluation in general, please see *The Logistics Handbook*.

1. When assessing availability of ACTs, include only formulations and manufacturers recommended by the WHO *guidelines for the treatment of malaria*.

Due to the history of drug resistance in malaria and dangers posed by counterfeit and substandard antimalarials, the international community has agreed to standards for medicines to be used for treatment. Despite recommendations by the WHO and leading experts, irregular, substandard, and potentially dangerous medicines can often be found in the public supply chain, especially in systems where health facilities have funding to purchase medicines locally. In determining whether a facility is adequately stocked with proper antimalarials, medicines other than those listed in the WHO *guidelines for the treatment of malaria*,[12] should not be counted because they are not considered appropriate or adequate for proper treatment. The current (2010) list includes:

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

In addition, the WHO creates a prequalified list of manufacturers of ACTs, based on unified standards of acceptable quality, efficacy, and safety. Medicines from manufacturers other than those

[12] Accessible here: http://www.who.int/malaria/publications/atoz/9789241547925/en/index.html. At the time of this writing, the second edition (2010) was the newest version of the guidelines.

listed on the WHO prequalified list[13] or SRA-approved should also be excluded or listed separately from performance indicators about availability.

2. Use the Index of Availability of ACTs indicator.

Some widely used ACTs, such as artemether plus lumefantrine and the co-blistered artesunate plus amodiaquine, are packaged into different presentations known as "weight bands" that are designated for ease of prescription for, and use by, different weight groups. These different presentations contain a single formulation and to be able to continue treatment, health care providers often cut or combine the different presentations should they stock out of a particular weight band. As such, a true assessment of a health facility's ability to provide treatment with an ACT should be more nuanced than a simple listing of the presence or stockout of a given presentation. This information must be analyzed to properly identify facilities stocked out of all presentations. For example, co-blistered AL is commonly divided into four presentations:

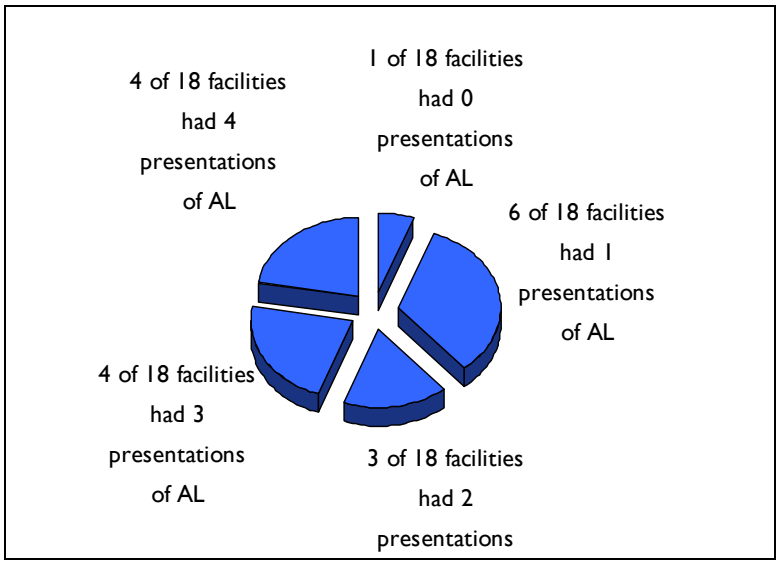
- 1×6
- 2×6
- 3×6
- 4×6

A facility would only be unable to treat malaria using the co-blistered presentation of AL if it were stocked out of all four presentations. Otherwise, it could cut or combine available presentation(s) for patients based on their weight. To represent this information fully, an M&E plan should include a standard availability indicator and an Index of Availability of ACTs indicator. Combined with traditional availability information for antimalarials, these two indicators will provide specific information about which presentations are stocked out, and information about the number of presentations available at any given facility. See the example below:

Figure 4. Number of Presentations Available

Facility	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Number of presentations available	3/4	4/4	2/4	1/4	1/4	0/4	1/4	1/4	4/4	2/4	3/4	2/4	3/4	3/3	1/4	1/4	4/4	4/4

[13] The list is updated regularly and can be accessed at http://apps.who.int/prequal/.



This indicator would not be applicable to an FDC product such as FDC AL since the presentation cannot be cut or combined for dispensing to patients in other weight bands.

3. Work to form stronger links between program and supply chain staff.

Supply chains and malaria programs are managed by different sets of personnel (LMUs or medical stores and NMCP, respectively), yet the information each holds can be very useful to the other. To better monitor and supervise the malaria supply chain, clarify roles and responsibilities of all staff involved. Throughout the supply chain, personnel should be designated with certain M&E responsibilities. Some of these can include:

- Receive and review logistics reports periodically and make decisions or inform decisionmakers about information received
- Routine supervision of service delivery points
  - Use a checklist of malaria-specific items to monitor capacity of health workers to interpret a prepared RDT[14]; preparation technique of RDT by health workers[14]; comparison of diagnostic and treatment records, if available[14]; maintenance of good blood safety practices[14]; storage conditions; rational use of ACTs and other antimalarials; proper recording and reporting.
  - Communicate with SDPs to determine challenges, such as product availability.
  - Identify problems that can be addressed immediately through on-the-job training.
- Identify and address bottlenecks upstream from the SDP and serve as an advocate for addressing problems in stock availability, additional resources (i.e., forms, staff) within the system to the SDP or NMCP.

[14] http://www.wpro.who.int/NR/rdonlyres/9F42AF75-AC81-48E5-AAA2-0FB9B630425C/0/RBMGFATMRDTApr17Fin2.pdf

4. Utilize established tools for malaria monitoring and supervision.

In addition to typical monitoring and supervisory tools recommended for all supply chains (e.g., LMIS reports, supervisory checklists, etc.), several specific tools focusing on unique characteristics of malaria supply chains are available:

- The End-Use verification tool (PMI)[15] was developed by PMI/USAID, the SPS project and the USAID | DELIVER PROJECT to assess the malaria supply chain, specifically spot checks of malaria commodities availability. Deployed in countries across Africa, the tool is intended to answer specific questions and trigger further action by NMCPs regarding these elements:
  - Number of facilities with stockouts, including ACT, SP, RDTs, drugs for treatment of severe malaria and proper case management of uncomplicated malaria, and LLIN where they are part of the regular supply chain
  - Expiry of ACTs and other products currently stocked at health facilities
  - Reconciliation between quantities of products ordered and received
  - Reconciliation of quantities of products received and physical inventory
  - Proper handling of products, including training levels, storage conditions, and regular supervision
  - Malaria case management, such as proportion of cases treated to number of treatments dispensed within a defined time frame, stratified by antimalarial drug used and level of care provided, number of patients presenting with fever, diagnosed with malaria, and broken down by age group, among others

  The End-Use tool is available in paper format and has also been developed for use with mobile phones via the EpiSurveyor platform. Conducting a supply chain assessment using mobile phones decreases time needed to input and analyze data, facilitating rapid use of data for decisionmaking.

  The End-Use tool provides a snapshot of logistics system fitness but does not act as an LMIS, Rather it is a way to validate data collected by the LMIS. Investments should be made to strengthen and improve the LMIS so national-level logistics data is routinely available. It is not intended to provide nationally representative data.
- The Pharmaceutical Management System Strengthening (PMSS) assessment tool, developed by PMI/USAID, SPS and the USAID | DELIVER PROJECT, gathers and assesses qualitative information relating to the malaria supply chain. Implementing partners complete the assessment annually. It consists of a written narrative and an Excel-based tool to which respondents assign a score and comment about and analyze strengths, weaknesses, opportunities, and threats of different key characteristics of the malaria supply chain, as they pertain to five categories:
  - Policy, law, regulation
  - Quantification and procurement
  - Storage, inventory management, and transportation

[15] Accessible through the Roll Back Malaria toolkit here: http://www.rollbackmalaria.org/toolbox/tool_PMIendUseVerification.html

- Prescribing and dispensing practices
- Financing and costs

Rational Use of Medicines

Purpose

Although not specified as part of the logistics cycle, rational use of medicines is essential to serving customers. As defined by the WHO, such use requires that "patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community."[16]

Rational use of medicines entails making a proper diagnosis; selecting the correct medicine; ensuring that the medicine meets unique patient needs; identifying the appropriate dose, formulation, and duration of therapy; dispensing correct medicines and offering relevant information to patients; and ultimately ascertaining that patients adhere to treatment. No matter how efficient the logistics cycle, without rational use, the customer is not well served.

Several stakeholders are responsible for rational use. These include prescribers and laboratory technicians making an accurate diagnosis, dispensers correctly dispensing prescribed medicine with clear directions on its use, and patients completing therapy. Furthermore, governments are responsible for developing and updating national treatment guidelines, national essential medicines lists and formularies, and supporting training programs on rational use of medicines.[17]

Recommendations

The following recommendations are for rational use of medicines and diagnostics as they relate to the supply chain. These consider special characteristics of malaria products.

1. Follow standard treatment guidelines (STGs).

STGs are suggested treatment protocols for the most optimal treatment of a specific clinical problem in a given setting, based on consensus by experts. These protocols can vary based on the level of treatment facility. There are clinical, public health, and supply chain benefits for adhering to STGs.

In some cases, there may be incentives *not* to follow STGs. For example, if ACTs are provided free in the system, community dispensers likely have a narrow profit margin associated with ACTs. But if they sell other products, such as SP, they can generate a fee. Thus, dispensers have a financial incentive to sell products not recommended by STGs. In other situations, patients may expect to receive treatment regardless of RDT results and may pressure health workers to dispense to or sell them any medicine, despite a negative test result.

Therefore, treatment and service policies may require review to address misaligned incentives and/or provide clearer guidance. Supervision and monitoring policies and practices also may need review.

[16] http://www.who.int/medicines/areas/rational_use/en/index.html

[17] http://www.who.int/medicines/areas/rational_use/rud_activities/en/index.html

To address the example above, STGs may need updating to incorporate new diagnostic tools like RDTs, to specify what dispensers should do in case of negative results, and how to better educate patients about rational use. For example, if policies allow, dispensers could provide antibiotics to treat possible pneumonia at the community level without further referral instead of dispensing SP to a febrile patient with a negative RDT result if the patient meets other diagnostic criteria of pneumonia.

2. Develop SOPs and guidelines specific to community health workers (CHWs) and prioritize their training, supervision.

CHWs play a particularly important role in diagnosis, treatment, and prevention of uncomplicated malaria in children under five and pregnant women in public and private sectors. Empowering these CHWs to provide appropriate and timely treatment within the first 24 hours significantly reduces mortality and morbidity in these vulnerable groups.

As more CHWs begin to use RDTs, rational use of ACTs should increase. RDT use has decreased inappropriate use of antimalarials and resulted in earlier referrals to health facilities for complicated malaria and other disease with fever as a symptom. Most countries have established policies for CHWs to manage malaria at the community level but have provided few guidelines for diagnosis and treatment and/or policies on referrals.

Tailoring national SOPs for CHWs can address differences between the community and facility environment. For example, CHWs usually have a lower level of education than health workers at health facilities, and SOPs for CHWs should include more illustrations and simpler writing so guidelines are easily understood and followed. Developing IMCI guidelines may be necessary to provide CHWs guidance on referrals of severe malaria cases.

Create supervision and monitoring policies to enhance and improve the work of CHWs and their adherence to STGs. As more CHWs perform RDTs and provide ACTs, include a process to review records. Training alone will not increase rational use at the community level. Policies, incentives, and observation of practices will further reinforce good performance.

3. If test results from RDTs are collected under the HMIS, subsequent treatment can be monitored and reviewed for rational use.

Usually, test results from RDTs are not collected in the same register as dispensed treatments. The information is in different places—at the laboratory for diagnosis and with the nurse or pharmacy for treatment. It may be possible to monitor rational use of antimalarials in a system that collects data on results of RDTs and treatments provided by comparing numbers of tests results (positive and/or negative) to numbers of treatments given. Options for feasibility of such monitoring should be assessed. See the LMIS chapter (recommendations 6 and 8) for further discussion of this topic.

Resources

Health Systems in Action: an eHandbook for Leaders and Managers. MSH. Cambridge, MA: Management Sciences for Health, 2010. Chapter 7. http://www.msh.org/resource-center/health-systems-in-action.cfm

WHO Guidelines for the Treatment of Malaria, second edition
http://www.who.int/malaria/publications/atoz/9789241547925/en/index.html

Managing Drug Supply (MSH and WHO), 1997.

System Design

Purpose

An infusion of resources has strengthened systems that manage malaria products. With countries managing an increasing number and volume of products, this demand can strain public health supply chains. As a result, it is even more important for countries to take a holistic view of public health systems and optimize their supply chains to use scarce resources most efficiently and effectively to ensure product availability.

A well-designed logistics system is fundamental in providing a continuous supply of good quality health products throughout the health system. The design should clearly describe how products and information move through different levels of the system. Specific guidance and procedures should be developed for:

- Logistics management information system
- Inventory control system
- Storage and warehousing
- Distribution system

A system design also clearly elucidates roles and responsibilities for each position and level involved in health product management and a structure for supervision.

Having the commitment of decisionmakers and key stakeholders in the health system is essential. Their endorsement and ongoing support are necessary for successful implementation. The level of complexity in health systems cannot be overcome unless all separate entities operating within the system are aligned and working together.

Earlier chapters in this guide have provided recommendations to consider during system design in terms of what information is collected and how (LMIS chapter), and ways of calculating resupply and establishing minimum and maximum stock levels (ICS chapter). Recommendations in this chapter focus on the *process* of designing a system that includes malaria products rather than the *content* of each design element.

Recommendations

The following recommendations consider the special characteristics of malaria products. For more information about system design in general, please see *The Logistics Handbook*.

1. **Include all relevant stakeholders in the design, from all levels of the health system and the private sector, if appropriate.**

Malaria medicines and products are used at all levels in the health system and all types of facilities, from large central-level hospitals down to the community level, from providers in referral facilities and nurses at ANC clinics to CHWs. In most situations, systems are best designed through facilitation of a design workshop. In this approach, key stakeholders and health workers who manage those products participate in designing the logistics system. Involving participants from program management and SDPs enables realistic decisions that consider policy and environmental factors. Including representatives from all system levels builds local capacity, enables designers to have complete information for decisionmaking, and facilitates ownership by users of the logistics system. Participants also play a key role as positive endorsers and champions when the system is implemented.

2. **Clearly define the system's scope, including types of products and involvement of public and/or private sectors.**

Consider for inclusion in the system all malaria products supplied routinely—ACTs, RDTs, SP, those to manage complicated malaria, those required for microscopy, and LLINs. However, in most cases, all products may not be included in the design (see recommendation 3 below for information on segmentation and integration).

If the logistics system is supplying public, private, or NGO-supported health facilities, stakeholders from these sectors must be involved with the design process. Furthermore, private health facilities often have policies separate from those of the public health system, and these must be considered during the design process.

3. **Consider unique product characteristics but seek opportunities to integrate with existing supply chains through a segmentation analysis.**

Very few countries or programs have designed or implemented a malaria-specific logistics system. Most often, malaria products are part of other logistics systems such as essential medicines or laboratory supply chains. Product integration, in which management of some or all logistics functions is combined in the same supply chain for different commodity categories, is a goal of many programs. However, product integration must be done by carefully considering specific characteristics of products and facilities that use them.

A large number and wide range of products is required for malaria programs. Segmentation involves dividing products into groups for supply chain management. This means that products are categorized by characteristics that affect how and where they are managed in the chain, of particular importance if malaria products are managed as part of a logistics system managing essential medicines. Examples of product segmentation include emergency response vs. predictable demand, products whose demand differs geographically, or full supply vs. non-full supply products.

For malaria products, this could mean that nets may be managed differently than antimalarials since they are often managed as part of campaigns rather than routine resupply. Another example is management of products for conducting malaria microscopy. Since those are likely to be managed at higher-level facilities with infrastructure and trained staff, they could be managed differently from ACTs and RDTs, which are likely to be at every health facility in the system and the community level. Another factor to consider when segmenting the supply chain for managing malaria products is SDP location and accessibility. If it is inaccessible during the rainy season, consider separate

design parameters. The segmentation process provides a rational framework for decisions about which products must be managed in which supply chains based on their unique product and customer characteristics. When supply chain decisions have been made through segmentation analysis, an LMIS, ICS, and other system elements can be designed or revised for each.

4. Adapt design to endemicity zone.

The burden of malaria is usually not distributed equally countrywide. Some geographic areas may experience high levels all year, while others are malaria-free or experience seasonal malaria. The system design should reflect realities of how and where malaria is experienced.

This may mean that distribution should be more frequent in endemic zones during malaria season while remaining constant in areas that experience malaria all year. This design may require more trucks for more frequent deliveries.

Another example is that maximum and minimum stock levels may be different for different parts of the country. Tailoring these levels to different areas could help better ensure that facilities are at reduced risk for stocking out or overstocking. For example, for seasonal areas, minimum and maximum levels could be higher or change at different times of year. For those that rarely have malaria cases, these levels could be set much lower while those that experience malaria all year could have constant stock levels throughout the year.

The ICS chapter offered different ways of calculating resupply. Different methods could be used for different areas. For those where malaria is prevalent all year, the last three months of consumption data could be used, while for those where malaria is seasonal, perhaps only the last month of consumption data could be used to calculate resupply.

Different designs for different geographic areas undoubtedly increases complexity of the logistics system, particularly for those at higher levels collecting, analyzing, and interpreting logistics data, conducting stock status analyses, or calculating resupply quantities. Whenever possible, automated systems should be utilized to facilitate decisionmaking for these staff. Throughout the system design process, designers should attempt to minimize the burden of work for facility-level staff.

5. Consider "parallel-type" systems during epidemics.

As countries increasingly implement preventive initiatives such as LLIN coverage and IRS, malaria will move from being endemic to epidemic. When status is epidemic, a logistics system must be responsive to sudden spikes in demand, without necessarily having consistent resupply processes in place. In this case, the logistics system can be designed so that throughout the year, only a small amount of products is on hand at facilities, while larger buffer stocks are held at the higher levels.

The logistics system for an epidemic is not necessarily "active" all year but has documented procedures for LMIS, ICSs, and distribution systems so the system can be activated when necessary. These systems manage a limited number of products and must move them quickly to the facility level. Procedures should be documented and provided to health facility staff so in the case of an epidemic, they know exactly what to do and can do it.

6. Consider alternate training models such as on-the-job training (OJT) to train expanded numbers of personnel at SDPs.

The success of a system design is defined by how effective and efficient the system is in practice, and it hinges on development of a thoughtful, properly resourced implementation plan. The plan

should include a training scheme, explaining the model for training, the number of facilities/individuals to be trained, and the training schedule. Training represents the most significant cost in implementing a system. Since malaria products are used at every level of the system, they entail significant training.

One way to implement the system is to train a group of trainers to conduct training workshops countrywide. Another method is on-the-job training (OJT), which involves health facility staff being trained one-on-one at their own facility rather than in a workshop environment. The trainer may also be the supervisor who provides OJT during a supervisory visit on how to order, store, and manage malaria products. This method is more time-consuming because a large number of staff members are not trained simultaneously, but it may be less expensive because per diem and training costs are lower. It can be particularly effective for malaria products because basically every facility in the country must be trained on the new system.

Appendix A

Characteristics of Commonly Used Antimalarial Medicines

Artemisinin-Based Combination Therapy (ACT)

The following ACTs are recommended by the WHO for treatment of uncomplicated falciparum malaria:

- artemether/lumefantrine
- artesunate + amodiaquine
- artesunate + mefloquine
- artesunate + sulfadoxine/pyrimethamine
- dihydroartemisinin + piperaquine
- All above formulations come in blister packs or as single formulations and/or fixed dose combination (FDC).

1. Artemether/Lumefantrine

Co-formulated or dispersible tablets contain 20mg of artemether (A) and 120mg of lumefantrine (L). AL is available as a single-source product under the proprietary name Coartem. In addition to its commercial presentation, it is available in different course-of-therapy packs for different population groups and is supplied at cost for public-sector use in endemic developing countries.

- AL is packaged in blister packs of 1x6 tablets, 2x6 tablets, 3x6 tablets, and 4x6 tablets.
- The packaging corresponds to a six-dose regimen to be given twice daily over three days.

Table 3. The WHO-Recommended Dosage of Artemether/Lumefantrine

Weight	Number of tablets to be taken per dose at 0, 8, 24, 36, 48, and 60 hours
5-14 kg	1 tablet
15-24 kg	2 tablets
25-34 kg	3 tablets
> 34 kg	4 tablets

2. Artesunate + Amodiaquine

Artesunate (AS) + amodiaquine (AQ) is available as an FDC or separate tablets. Separate scored tablets contain 50mg of artesunate and 153mg base of amodiaquine. Formulation is available from different manufacturers in separate blister packs or single course-of-therapy packs. Scored tablets must be cut and crushed for children not yet one year old.

- AS+AQ is co-packaged in a blister pack that contains a row of artesunate tablets and row of amodiaquine tablets in these presentations: 3 tablets of artesunate 50 mg + 3 tablets of amodiaquine 153mg, 6 tablets of artesunate 50mg + 6 tablets of amodiaquine 153mg, or 12 tablets of artesunate 50mg + 12 tablets of amodiaquine 153.
- Each blister pack is equivalent to one treatment, and a box contains 10 or 25 packs.
- The recommended treatment is 4 mg/day of artesunate and 10mg/day of amodiaquine for 3 days, roughly equivalent to 1, 2 or 3 tablets per day based on the patient's weight.

The treatment regimen has these challenges:

- A high pill burden and thus higher potential for noncompliance to treatment course
- Because amodiaquine is known to cause unpleasant side effects, patients might take only the artesunate part, increasing risk of developing resistance.

Table 4. The WHO-Recommended Dosage of AS+AQ

Weight	Number of tablets of artesunate to be taken daily for 3 days	Number of tablets of amodiaquine to be taken daily for 3 days
5-11 months	25mg (1/2 tablet)	76mg (1/2 tablet)
1-6 years	50mg (1 tablet)	153 mg (1 tablet)
7-13 years	100mg (2 tablets)	306mg (2 tablets)
>13 years	200mg (4 tablets)	612mg (4 tablets)

Artesunate / Amodiaquine FDC

Sanofi-Aventis developed an FDC of AS/AQ that has been prequalified by the WHO. The active ingredients are formulated in one bi-layered tablet. This physically separates ingredients to avoid interaction and instability. Advantages of the new formulation are:

- Delivery of a fixed dose, avoiding underdosing or overdosing and eliminating resistance risks of monotherapy
- A simple dosing regimen—one or two tablets daily, making patient compliance more likely
- Adapted presentations for all ages—four different presentations enabling dosing based on body weight and age

- Small, soluble tablets for infants and children, the most at-risk population, that can be administered in water, liquids, or semi-liquid food

All these are supplied in boxes containing 25 blisters. Sanofi-Aventis has developed training and information, education, and communication (IEC) materials that will be provided free to countries requesting them.

Table 5. The WHO-recommended Dosage of AS/AQ FDC

Weight	Number of tablets of AS/AQ FDC to be taken daily for 3 days
5-11 months	artesunate 25mg + amodiaquine 67.5 mg (3 tablets)
1-5 years	artesunate 50mg + amodiaquine 135mg (3 tablets)
7-13 years	artesunate 100mg + amodiaquine 270mg (3 tablets)
>13 years	artesunate 100mg + amodiaquine 270mg (6 tablets)

3. Artesunate + Sulfadoxine/Pyrimethamine

Separate scored tablets contain 50mg of artesunate and 500mg of sulfadoxine + 25mg pyrimethamine. Co-formulated tablets are not available. Different manufacturers offer separate blister packs as single course-of-therapy packs or packs of 10 or 25 treatments. Scored tablets must be cut and crushed for children not yet one year old.

Table 6. The WHO-recommended Dosage of Artesunate + Sulfadoxine/Pyrimethamine

Weight	Number of tablets of artesunate to be taken daily for 3 days	Number of tablets of sulfadoxine/pyrimethamine to be taken on day 1 only
5-11 months	25mg (1/2 tablet)	250mg/12.5mg (1/2 tablet)
1-6 years	50mg (1 tablet)	500mg/25mg (1 tablet)
7-13 years	100mg (2 tablets)	1000mg/50mg (2 tablets)
>13 years	200mg (4 tablets)	1500mg/75mg (3 tablets)

4. Artesunate + Mefloquine

Separate scored tablets contain 50mg of artesunate and 250mg base of mefloquine. Co-formulated tablets are not available. Manufacturers offer separate blister packs or single course-of-therapy packs. Scored tablets must be cut and crashed for children not yet one year old.

- AS/MF is co-packaged in a blister pack tablets in these presentations: 3 tablets of artesunate + 1 tablet of mefloquine, 6 tablets of artesunate + 2 tablets of mefloquine, 12 tablets of artesunate + 3 tablets of mefloquine, and 12 tablets of artesunate + 5 tablets of mefloquine.

Table 7. The WHO-recommended Dosage of Artesunate + Mefloquine

Weight	Number of artesunate tablets to be taken daily for 3 days	Number of mefloquine (250mg) tablets to be taken daily		
		Day 1	Day 2	Day 3
5-11 months	25mg (1/2 tablet)	0	125mg (1/2 tablet)	0
1-6 years	50mg (1 tablet)	0	250mg (1 tablet)	0
7-13 years	100mg (2 tablets)	0	500mg (2 tablets)	250mg (1 tablet)
>13 years	200mg (4 tablets)	0	1,000mg (4 tablets)	500mg (2 tablets)

5. Rectal Artesunate

The appropriate single dose of artesunate given by suppository should be administered rectally as soon as the presumptive diagnosis of severe malaria is made. For adults, give one or more artesunate suppositories as indicated in Table 6.

- Suppositories contain 50mg of artesunate for children and 200mg for adults.
- Dosage will vary according to body weight (please see below), but the recommended treatment for children is 5mg/kg twice daily for day 1 and 5mg/kg once daily for days 2 to 5. For adults, the recommended regimen is 200mg twice daily for day 1 and 200mg once daily for days 2 to 5.
- One pack contains six or 12 suppositories.

Table 8. Dosage for Pre-referral Treatment for Adult Patients (16 years and older)

Weight (kg)	Artesunate dose	Regimen (single dose)
< 40	10mg/kg body weight	Use appropriate number of 100mg rectal suppositories
40-59	400mg	One 400mg suppository
60-80	800mg	Two 400mg suppositories
>80	1,200mg	Three 400mg suppositories

Table 9. Dosage for Pre-referral Treatment for Children (2-15 years) Weighing at Least 5kg

Weight (kg)	Age	Artesunate dose	Regimen (single dose)
5-8.9	0-12 months	50mg	One 50mg supp
9-19.9	13-42 months	100mg	One 100mg supp
20-29.9	43-60 months	200mg	Two 100mg supp
30-39.9	6-13 years	300mg	Three 100mg supp
>40	>14 years	400mg	One 400mg supp

6. Artemether 80mg, 40mg, and 20mg Ampoules

Severe malaria in adults and children can be treated with artemether intramuscular injections. The daily dosage is 3.2 mg/kg body weight on the first day followed by 1.6mg/kg body weight to a maximum of seven days. Once the patient can tolerate oral therapy, treatment should be switched to a complete dosage of oral ACTs.

Packaging for each artesunate injection is in boxes, and each contains one vial of artesunate plus one ampoule of 5 percent sodium bicarbonate.

Quinine

Quinine was first used to treat malaria in Rome in 1631. Whereas many antimalarials are prescribed in terms of base, for historical reasons, quinine doses are often recommended in terms of salt, usually sulfate for oral use and dihydrochloride for parenteral use. Various preparations include hydrochloride, dihydrochloride, sulfate, bisulfate, and gluconate. This makes quinine dosing very complicated because each salt has a different weight.

The following amounts of each form are equal:

- quinine base 100mg
- quinine bisulfate 169mg
- quinine dihydrochloride 122mg
- quinine hydrochloride 122mg
- quinine sulfate (actually $[quinine]_2H_2SO_4 \cdot 2H_2O$) 121mg
- quinine gluconate 160mg

All quinine salts may be given orally or intravenously, and quinine gluconate may also be given intramuscularly or rectally.

Table 10. Dosage of Quinine Tablets

Age	Weight	Dose (every 8 hours for 7 days)
3 months to 1 year	5-10kg	75mg (1/4 tab)
1-5 years	10-18kg	150mg (1/2 tab)
5-7 years	18-24kg	225mg (3/4 tab)
7-10 years	24-30kg	300mg (1 tab)
10-13 years	30-40kg	375mg (1 ¼ tab)
13-15 years	40-50kg	450mg (1 ½ tab)
Older than 15 years	Over 50kg	600 (2 tab)

The intravenous dose of quinine is 8 mg/kg of quinine base every eight hours, the intramuscular dose is 12.8 mg/kg of quinine base twice daily, and the rectal dose is 20 mg/kg of quinine base twice daily. Treatment should last seven days.

Quinine formulations should be stored at room temperature and away from excess heat and moisture. Shelf life of quinine formulations is five years.

Sulphadoxine/Pyrimethamine (SP) 500mg/25mg

Sulfadoxine and pyrimethamine are folic acid antagonists. *P. falciparum* malaria clinically resistant to SP occurs frequently in parts of Southeast Asia and South America and is prevalent in East and Central Africa. Therefore, according to the most recent WHO recommendations, use of SP is restricted to IPTp. This requires administration of a complete curative dose of an antimalarial medicine at predefined intervals during pregnancy—typically in two doses and from the second trimester, at least one month apart—regardless of whether the pregnant women are infected with malaria.

- SP 500mg/25mg comes in tablet form, and a single dose comprises three tablets.
- Packaging is in packs of 1,000 tablets with 28 packs per carton.

Appendix B

Malaria Forecasting Guidance

Suggested Approaches to Forecasting for Malaria Programs in the Absence of Consumption Data

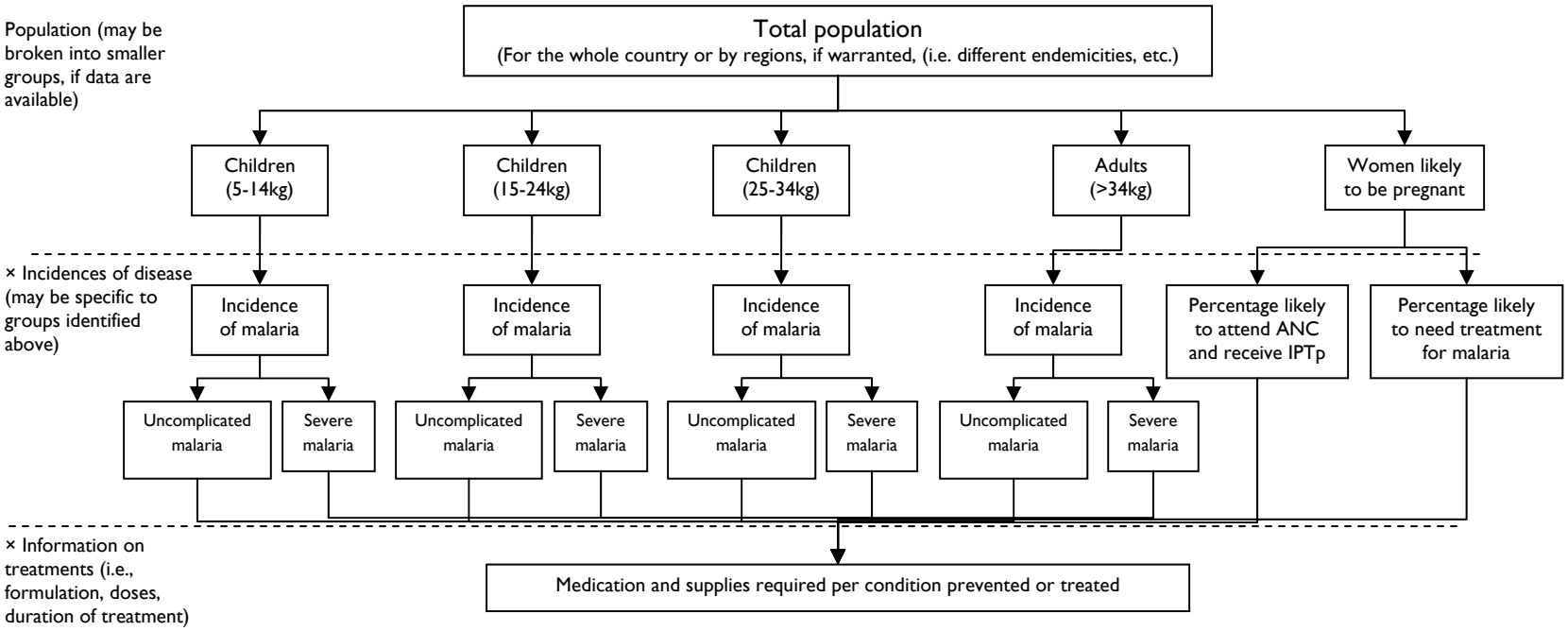
In many countries where we work, consumption data may not be available or may not reflect future use due to changes in malaria programs (i.e., RDT scale-up, LLIN and IRS campaigns, or changes in STGs). While every country will have a different context and require an appropriately tailored strategy, USAID | DELIVER PROJECT suggests two approaches to conducting a forecast of antimalarials based on non-consumption data that may be available. In the second part of this appendix, reference and proxy data are made available.

Morbidity Data

Follow the illustrative forecasting tree in figure 1 and populate with data available. You may have fewer or more branches in the forecasting tree than provided here. Each level of the tree is multiplied by the next to determine the final quantities of medicines and supplies needed. Data should include:

- Total population by weight band or age group used in recommended ACT, and population of women likely to be pregnant during the time reviewed
- Malaria incidence by groups organized above
- Treatments used by groups and diseases organized above. These should come from national STGs or by reviewing prescribing practices if these practices are substantially different from STGs and are not anticipating considerable changes, such as trainings.

Figure 5. Morbidity Forecasting Tree (Illustrative)



Services Data

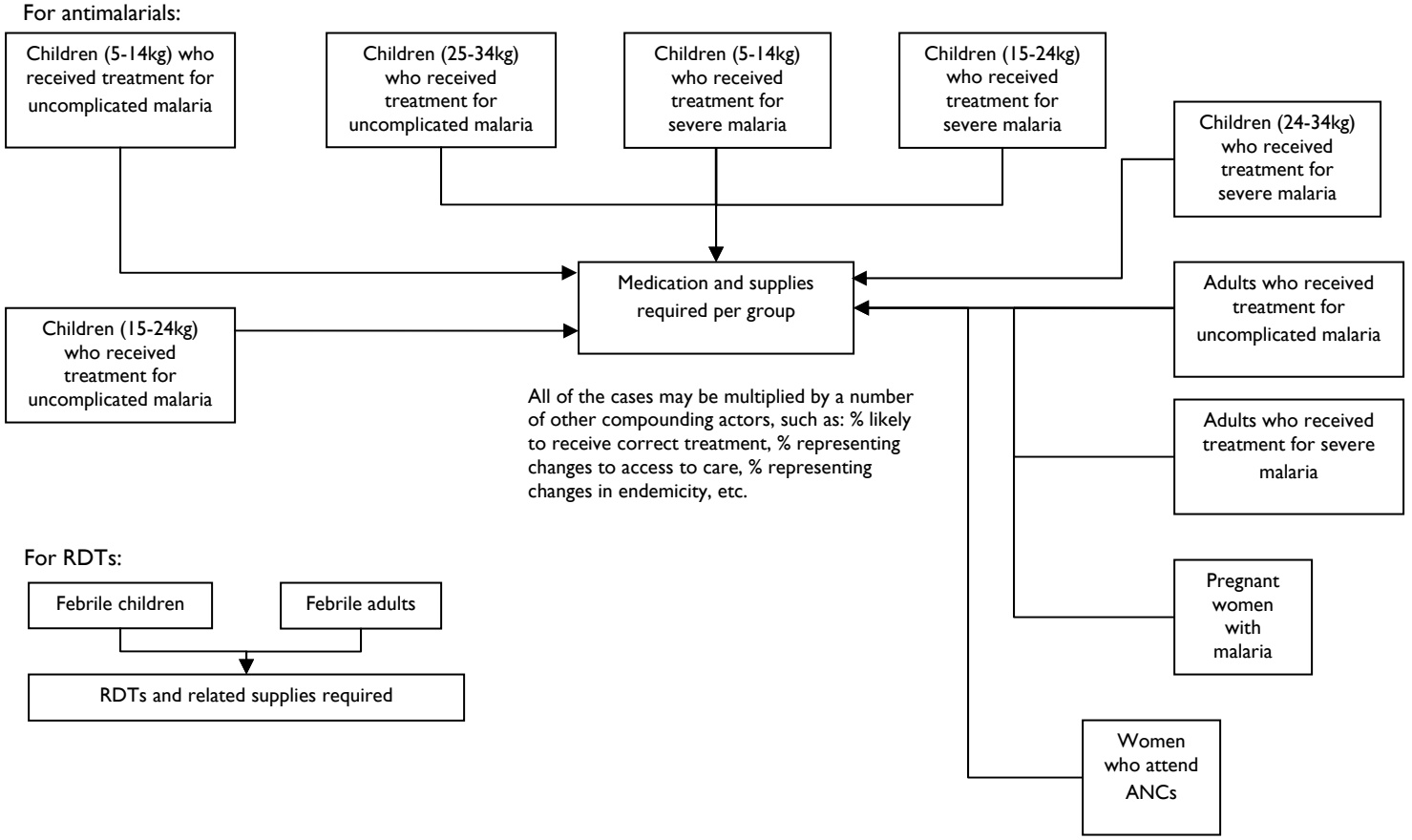
With this method, the number of cases for each condition is multiplied by medicines and supplies needed to determine the final quantity.

- For ANC and other antimalarial forecasting:
  - Malaria cases (by weight band or age group used in recommended ACT)
    - If data on malaria cases are not available, a percentage of fever episodes may be used to estimate malaria cases (see proxy data section below).
  - Number of suspected malaria cases with parasitological confirmation (treated and untreated) by groups organized above, if available.
  - Number of suspected malaria cases with negative parasitological confirmation (treated and untreated) by groups organized above, if available. This information may be useful if high numbers of negative results are receiving some type of treatment.
  - Number of severe malaria cases (as a percentage or figure of malaria cases by groups organized above, if available.
  - Number or percentage of women attending ANCs.
  - Number of pregnant women with malaria or treated for it in the past year.
  - Treatments used by groups and diseases organized above. These should come from national STGs or by reviewing prescribing practices if those are substantially different from STGs and not anticipating considerable changes, such as trainings.
- For RDT forecasting:
  - Number of cases tested by microscopy or RDT by groups organized above, if available, or
  - Number or percentage of fever cases tested by groups organized above, if available.

Notes:

- It's important that all patients suspected of having malaria be tested for parasitological confirmation. Forecasts for RDTs should therefore be much higher than those for patients who actually have malaria and receive treatment.
- If a scale-up of RDTs is planned for a new area, you may want to determine an upper limit for your forecast by determining the quantity of tests that a health worker can perform in a given period of time (e.g., working hours in a day).

Figure 6. Service Data Tree (Illustrative)



Reference Materials

General References

Possible sources of malaria data:

1. NMCP reports
2. RBM country facts website: http://www.rbm.who.int/countryaction/index.html
3. The WHO malaria country profiles website: http://www.who.int/malaria/publications/country-profiles/en/index.html
4. Health center sampling, which can be extrapolated to areas with similar transmission and/or service patterns.

Reference data for population:

Population of children from total population in sub-Saharan Africa[18]:

Children up to 4 years old: 16.5% of the total population

Children 5-9: 14.2% of the total population

Children 10-14: 12.3% of the total population

Children under 15: 43% of the total population

Relating age with weight or vice versa.

Girls under 5: http://www.who.int/childgrowth/standards/sft_wfa_girls_p_0_5.pdf

Boys under 5: http://www.who.int/childgrowth/standards/sft_wfa_boys_p_0_5.pdf

Girls 5-10: http://www.who.int/growthref/sft_wfa_girls_perc_5_10years.pdf

Boys 5-10: http://www.who.int/growthref/sft_wfa_boys_perc_5_10years.pdf

Age	Girls (median weight in kg)	Boys (median weight in kg)
0	3.2	3.3
1	8.9	9.6
2	11.5	12.2
3	13.9	14.3
4	16.1	16.3
5	18.2	18.3
6	20.2	20.5
7	22.4	22.9
8	25	25.4
9	28.2	28.1
10	31.9	31.2

[18] U.S. Census Bureau, International Data base. http://www.census.gov/ipc/www/idb/informationGateway.php

Proxy Data (Refer to Studies for Detailed Information)

Uncomplicated malaria:

If the total of malaria cases is not available but the total of fever cases is, you may use the following proxy data to determine the percentage of fever cases caused by malaria[19]. Different stratifications are listed below, so you may choose one that best fits your situation. Multiply fever cases by the appropriate percentage to find the number of malaria cases. Remember that ACTs may not treat all malaria cases. That figure may be more or less with over- or under-treatment. The year 2000 was selected to represent the start of increased malaria control efforts.

Fevers associated with *P. falciparum* parasitaemia (PFPf) in sub-Saharan Africa:

- Median of PFPf across all age groups, seasons and setting is 35% (44% before 2000; 22% afterward).

PFPf by age group:

- 36% for children under five years old (56.8% before 2000; 21.9% afterward).
- 26% for those above five (33.3.% before 2000; 17.5% afterward).

PFPf by season:

- 37% in rainy season (54.9% before 2000; 32.6% afterward).
- 5% in dry season (4.6% before 2000; 11.9% afterward).

PFPf by setting:

- 38% in rural areas (45.1% before 2000; 16.8% afterward).
- 31% in urban areas (39.8% before 2000; 25.7% afterward).
- 35% in primary care settings (43.2% before 2000; 25.8% afterward).
- 40% in hospitals (52.3% before 2000; 15.1% afterward).

[19] D'Acremont *et al.*: Reduction in the proportion of fevers associated with *Plasmodium falciparum* parasitaemia in Africa: A systematic review. *Malaria Journal* 2010, 9:240.

Severe malaria:

If no data exist on percentage of malaria cases diagnosed as severe malaria, one of the following studies may be similar enough to the area forecast to use as a proxy.

Study	Dzeing-Ella (2005)[25]		Reyburn (2004)[22]		Mockenhaupt (2004)[24]		Chanda (2009)[20]	
Country	Gabon		Tanzania		Northern Ghana		Zambia	
Entomological inoculation rate (bites /person year)	50		1-300		300			
Intensity of malaria transmission	hyperendemic		range from low to high		not given		High and low transmission seasons (March-November 2005)	
Setting	country's tertiary referral hospital (children up to10 years)		six district, one regional and one referral hospital (children under 13)		Teaching hospital (children 6 months to 9 years)		12 facilities in four districts	
Percentage of positive malaria cases	uncomplicated	severe	uncomplicated	severe	uncomplicated	severe	uncomplicated	severe
	81.5%	18.5%	33.1%	66.9%	38.2%	61.8%	98.5%	1.5%

Please note that most of the studies were at referral facilities, so the percentage of severe malaria cases is much higher than would be found at lower-level facilities.

[20] Chanda et al.: Cost-effectiveness analysis of the available strategies for diagnosing malaria in outpatient clinics in Zambia. Cost Eff Resour Alloc. 2009; 7:5.

Several studies have shown that as the intensity of *P. falciparum* transmission increases, the mean age of severe malaria decreases.[21] Refer to the study for detailed information.

P*f*PR (transmission intensity)	**Percentage in less than one-year-olds admitted to hospitals for severe malaria**
>40% (mesoendemic to hyperendemic)	40%
5-39% (Hypoendemic to mesoendemic)	20%
<5% (hypoendemic)	10%

Hypoendemic (<10%), Mesoendemic (10-50%), Hyperendemic (50-75%)

Proxy percentage of patients with severe malaria conditions:

Condition	**Average percentage of severe malaria patients with condition from the referenced studies**[22, 23, 24, 25]
Severe anemia	47.63%
coma or convulsions	23.4%
respiratory distress	22.7%
hyperlactatemia	29.47%
hypoglycemia	8.77%

[21] Okiro *et al.*: Age patterns of severe paediatric malaria and their relationship to *Plasmodium falciparum* transmission intensity. *Malaria Journal* 2009 8:4.

[22] Reyburn, *et al.*: Overdiagnosis of malaria in patients with severe febrile illness in Tanzania: a prospective study. *BMJ 2004*, doi:10.1136/bmj.38251.658229.55.

[23] Oduro, *et al.*: Severe falciparum malaria in young children of the Kassena-Nankana district of northern Ghana. *Malaria Journal* 2007, 6:96.

[24] Mockenhaupt, *et al.*: Manifestation and outcome of severe malaria in children in northern Ghana. A*m. J. Trop. Med. Hyg.* 2004, 7(2).

[25] Dzeing-Ella, *et al.*: Severe falciparum malaria in Gabonese children: clinical and laboratory features. *Malaria Journal* 2005, 4:1.

Impact of Interventions:

Authors	Bouyou-Akotet, et al[26]	Otten, et al27		Barnes, et al28	
Date published	December 2009	January 2009		October 2009	
Country	Gabon	Rwanda	Ethiopia	KwaZulu-Natal, South Africa	Zambia
Period under review	2000-08	reference period of 2001-05 in Rwanda and 2001-06 in Ethiopia, intervention period of 2007		2001-05	Reference period of 2001-02, intervention period of 2006
Setting	Largest hospital in-country, malaria unit	Nine hospitals and 10 national health centers from all five provinces	One hospital and one outpatient health center of two districts in four major regions		
Population	children <11, inpatient and outpatient	Inpatients of all ages, further segregated by under and over 5			
Interventions	ACTs in 2002; free ACTs and ITNs in 2005; ITN coverage reached 49.8% in 2006 and 57% in 2008.	LLIN and ACT in late 2006	LLIN distribution from 2005-07; ACTs launched in 2005	ACTs launched in 2001; IRS before and strengthened after 2005	ACTs launched in 2003 and in all districts by 2004; IRS from 2003-07; ITN distribution from 2003-05
Reductions	Percentage with malaria in 2000 was 45%, dropped to 12% in 2007 and 15% in 2008.	Inpatient cases declined 64% for <5 and 59% for 5+; laboratory-confirmed cases declined 63% for <5 and 54% for 5+.	Inpatient cases declined 83% for <5 and 69% for 5+; laboratory-confirmed cases declined 3% for 5+ (too little data for <5).	Malaria-related outpatient cases reduced by 85% in 2001 and by 97% by 2003.	Rates of inpatient malaria cases decreased by 61% from 2001-06; 91%-93% reduction in severe malaria cases at health facilities from 2002-05.

[26] Bouyou-Akotet, *et al.*: Evidence of decline of malaria in the general hospital of Lireville, Gabon from 2000-2008. *Malaria Journal* 2009, 8:300.

[27] Otten, *et al.*: Initial evidence of reduction of malaria cases and deaths in Rwanda and Ethiopia due to rapid scale-up of malaria prevention and treatment. *Malaria Journal* 2009, 8:14.

[28] Barnes, *et al.*: Impact of the large-scale deployment of artemether/lumefantrine on the malaria disease burden in Africa: case studies of South Africa, Zambia and Ethiopia. *Malaria Journal* 2009, 8(Suppl 1):SB.

Impact of RDTs:

Study	Uzochukwu[29]	Ansah[30]	Chinkhumba[31]	Kyabayinze[32]	Bisoffi[33]	Msellem[34]
Average percentage of prescriptions for febrile patients with ACTs	Before intro of RDTs: 1.5% (79% placed on chloroquine and 19.5% on SP) After intro of RDTs: 86% (chloroquine dropped to 11.5% and SP to 2.5%)	In clinics that previously had microscopy, slight change was from 54.6% to 53.7%. In clinics that did not, RDT arm received fewer ACTs—57.8% compared to clinical arm (73.6%)				Before RDTs: 85%; after: 36%
Average percentage of prescriptions for febrile patients with antibiotics	Before RDTs: 75% after RDTs: 62%	3.1% with clinical arm; 14.1%-14.5% with RDT and microscopy arms				Before RDTs: 27%; after: 37%
Percentage of positive RDT result that received ACTs	100%	98.3%-99.6%	98%		95.6%-98.2%	
Percentage of negative RDT results that received ACTs	74%	46%-49.5%	58%	30% (children <5 were 2-3 more times likely to receive antimalarials)	79.8%-82.6%	
Percentage of positive RDT result that received antibiotics		11.2%-14.4%			46.2%-61%	

[29] Uzochukwu, et al. :Improving rational treatment of malaria: perceptions and influence of RDTs on prescribing behavior of health workers in southeast Nigeria. PLoS ONE 2011, 6:1.

[30] Ansah, et al.: Rapid testing for malaria in settings where microscopy is available and peripheral clinics where only presumptive treatment is available: a randomized controlled trial in Ghana. BMJ, 340:c930.

[31] Chinkhumba, et al.: Comparative field performance and adherence to test results of four malaria rapid diagnostic tests among febrile patients more than five years of age in Blantyre, Malawi. Malaria Journal 2010, 9:209.

[32] Kyabayinze, et al. Use of RDTs to improve malaria diagnosis and fever case management at primary health care facilities in Uganda. Malaria Journal 2010, 9(Suppl 2):P18.

[33] Bisoffi, et al. Rapid malaria diagnostic tests vs. clinical management of malaria in rural Burkina Faso: safety and effect on clinical decisions. A randomized trial. Tropical Medicine and International Health 2009, 14:5.

[34] Msellem, et al.: Influence of rapid malaria diagnostic tests on treatment and health outcome in fever patients, Zanzibar–A crossover validation study. PLoS ONE 2009, 6:4.

Percentage of negative RDT results that received antibiotics		28.6%-35%			54.7%-59.9%	
Other notes	Average number of prescriptions dropped from 6.2 to 3.3 after introduction of RDTs; number of medicines per prescription for positive RDTs were 2.1 and for negative RDTs were 3.8.			90% of patients were offered RDT; 38% reduction in antimalarial prescriptions.		

Appendix C

Procurement Checklist (adapted from the WHO Global Malaria Programme)[35]

STEP 1	Select safe, effective antimalarial medicines Select medicines in accordance with WHO Guidelines for the Treatment of Malaria, national standard treatment guidelines, and program needs.
STEP 2	Estimate requirements Investigate opportunities for joint quantification. Quantify national need for treatment courses. Forecast numbers of packages needed, based on available funding. Prepare delivery schedules based on shelf life and storage and distribution capacity.
STEP 3	Secure funding Calculate the expected total cost of procuring and distributing required quantities of products (determined in STEP 2). Identify and secure funding (national budget, subsidies, donors).
STEP 4	Define product specification List required product formulations (see STEP 1). List required quality specifications.
STEP 5	Select procurement method and prepare tender documents Determine tender format and scope. Prepare tender documentation with invitation to bid, instructions to bidders, technical specifications, and schedule of requirements.

[35] http://whqlibdoc.who.int/publications/2010/9789241598927_eng.pdf

STEP 6	Invite tenders In a fair, transparent process, identify and contact potential suppliers of stringently assessed products approved by the WHO PQP or an SRA. If too few such products are on the market, identify potential suppliers of alternative products and communicate the call for tender among them.
STEP 7	Investigate bid responses and validity Conduct a preliminary evaluation of offers on the basis of predetermined criteria. Examine suppliers' records, administrative information and licensing status.
STEP 8	Evaluate product quality Identify offers that comply fully with the technical specifications
STEP 9	Evaluate bids commercially From bids recommended on the basis of technical evaluation, select that which offers optimal value in terms of service and financial and logistic conditions. Tender evaluations should be based on criteria specified in tender documents (see STEP 4).
STEP 10	Prepare contracts On the basis of tender documentation and results of bid evaluation, prepare contracts with selected supplier(s). Include additional or specific requirements, such as language or packaging for the country of use.
STEP 11	Conduct preshipment inspection and quality control Identify opportunities for joint quality control testing. Contract a qualified laboratory (preferably WHO-prequalified or ISO-17025- accredited) in a competitive process. Ensure sampling, batch testing, handling of results, and reporting according to agreed procedures and funders' requirements.
STEP 12	Port clearance and receipt For international procurement, liaise with the supplier, consignee, and staff at port of entry before each shipment. On receipt, check products against orders and specifications. Report procurement outcomes as required by program and funders.
STEP 13	Post-shipment quality control Identify opportunities for joint quality control testing. Contract a qualified laboratory (preferably WHO-prequalified or ISO-17025-accredited) in a competitive process. Ensure sampling, batch testing, handling of results, and reporting according to agreed procedures and funders' requirements.

STEP 14	Storage and distribution Liaise with stock control officers or warehouse staff responsible for storage and distribution of medicines in accordance with good practice.
STEP 15	Monitor supplier performance Check that deliveries match orders over time. Keep a record of lead times and other procurement outcomes.
STEP 16	Monitor variations Ensure continuing compliance with contractual specifications. Handle any changes as contractually agreed.

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