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MALAWI: ARV SUPPLY CHAIN INTEGRATION

AN ASSESSMENT OF THE ARV AND ESSENTIAL MEDICINES LOGISTICS SYSTEMS

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**AN ASSESSMENT OF THE ARV AND ESSENTIAL
MEDICINES LOGISTICS SYSTEMS**

USAID | DELIVER PROJECT, Task Order 1

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Abstract

An assessment of the ARV and integrated essential medicines logistics systems was carried out from May 19 through June 6, 2008 by a consultant team from the USAID | DELIVER Project. The purpose of the activity was to determine whether the antiretroviral (ARV) supply chain — of which several components are managed vertically to the Central Medical Stores (CMS) system — can be integrated into the CMS system without a loss of service. The report suggests that the CMS and related public sector agencies do not currently possess adequate technical, organizational, and human resource capacity to integrate procurement, inventory control, distribution, and data collection and management of ARVs without compromising the current quality of service. As such, these functions should remain vertical to the CMS until suggested reforms have been enacted and subsequent capacity developed to carry out these procurement and supply management (PSM) functions for ARVs on behalf of the Malawi Minister of Health's antiretroviral therapy (ART) program. The report details a series of recommendations to address the gaps in capacity of the CMS system. The recommendations will require a commitment to a series of steps that, if implemented, will make possible a phased approach to simultaneously begin integrating ARV distribution and improve PSM capacity for essential drugs.

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ACRONYMS

3PL	Third Party Logistics Agent
ART	antiretroviral therapy
ARV	antiretroviral
CABS	Common Approach to Budget Support
CCM	country coordinating mechanism
CHAM	Christian Health Association of Malawi
CMS	Central Medical Stores
CP	Cooperating Partner
CPT	co-trimoxazole prophylaxis therapy
CS	commodity security
DAS	development assistance strategy
DfID	Department for International Development (British)
DHO	District Health Office
DHTSS	Department of Health Technical Support Services
EHP	Essential Health Package
EML	essential medicines list
EU	European Union
FDC	fixed-dose combination
GFATM	Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria
GNI	gross national income
GOM	Government of Malawi
GPRM	global price reporting mechanism
HDG	Health Donor Group (Malawi)
HR	human resources
ICB	international competitive bid
LMIS	logistics management information system
M&E	monitoring and evaluation
MBC	Medical Buying Committee
MDG	Millennium Development Goal

MK	Malawian kwacha (monetary unit)
MOU	Memorandum of Understanding
MOF	Ministry of Finance
MOH	Ministry of Health
NAC	National AIDS Committee
NDC	non-drug consumable
NDRA	National Drug Regulatory Authority
NGO	nongovernmental organization
ODPP	Office of Director of Public Procurement
OI	opportunistic infection
POW	Program of Work
PMCT	preventing mother-to-child transmission
PR	principal recipient
PSM	procurement and supply management
RCC	rolling continuation channel
RDF	revolving drug fund
RMS	Regional Medical Stores
SCM	supply chain management
SDP	service delivery point
SKU	stock keeping unit
SOP	standard operating procedure
STG	standard treatment guideline
SWAp	sector wide approach
TOR	terms of reference
TWG	technical working group
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WDI	World Development Index
WHO	World Health Organization

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The authors of this report would like to thank the Government of Malawi (GOM), the Ministry of Health (MOH), and the Central Medical Stores (CMS) for the opportunity to conduct the assessment of the ARV and the essential medicines supply chains. The assessment revealed the progress Malawi has made in providing ART to its citizens, when and where they are needed and in the right quantity and of good quality — the definition of commodity security.

With each challenge to the system identified in the assessment, opportunities also presented themselves. It is hoped that issues identified in this report will inform and motivate procurement and supply management (PSM) stakeholders to further define these opportunities in a subsequent work planning process.

The authors would like to thank the individuals consulted for the technical report (see Table 2.1 and Annex 2) for their candor and time spent with us in discussing at length both what is “going right” as well as the improvements that can be made to improve access for ART products and other essential medicines.

We would also like to express our gratitude to the USAID | DELIVER office in Malawi, especially Jayne Waweru, for their support in organizing the assessment visit and for providing expert technical input and guidance on all aspects of the study.

The U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) through the United States Agency for International Development (USAID) provided financial support to the USAID | DELIVER Project to undertake this work. We are grateful for their continued commitment to HIV treatment and prevention and for underwriting that commitment in Malawi and elsewhere.

EXECUTIVE SUMMARY

An assessment of the ARV and integrated essential medicines logistics systems was carried out from May 19 through June 6, 2008 by the USAID | DELIVER Project. The purpose of the activity was to determine whether the ARV supply chain — managed vertical to the Central Medical Stores (CMS) medicine distribution system — can be integrated without resulting in a loss of service to ART patients. To make this determination, performance assessments of each system were carried out and recommendations put forth to define *if*, *how*, and *when* ARV supply chain functions can be phased into the CMS essential medicines system.

MAIN FINDINGS

1. The CMS and related public sector agencies do not currently possess adequate technical, organizational, and human resource capacity to integrate procurement, inventory control, distribution, and data collection and management of ARVs without compromising the current quality of service. As such, these functions should remain vertical to the CMS until suggested reforms have been enacted and subsequent capacity developed to carry out these PSM functions (for ARVs) on behalf of the MOH's ART program.
2. The HIV/AIDS Unit and other public sector entities are performing adequately with regard to logistics and patient data management and quantification of ARV consumption and estimation of future needs. Nonetheless, the sustainability of this function as the ART program grows is a concern. Consequently, the recommendations provide an approach that both helps maintain and improve quality of service of ART provision and details capacity-building measures within the CMS, the HIV/AIDS Unit, and other agencies to phase-in integration over time, subject to improvements in performance measurement indicators included in this report.

METHODOLOGY

1. The analysis consisted of both upstream components (e.g., procurement and forecasting) and downstream supply chain functions (e.g., inventory management, in-country transportation, and stock status). Data collection efforts were *primarily* focused on procurement and warehousing (inventory control and transportation) — functions managed outside the CMS system by UNICEF.
2. The second tier of focus was on logistics management information systems (LMIS) and forecasting. These functions are partially integrated, as they are the primary responsibility of the MOH's HIV/AIDS Unit, though outside of the CMS distribution system.
3. The third area of focus was on financing and the policy environment in which the supply chains operate. These functions are both critical to PSM but outside the traditional systems-based methodology in which logistics assessments are usually carried out. Nonetheless, because each is connected to the other, the methodology was designed to ensure the team obtained the breadth and depth of information to make informed recommendations.

Data were obtained through pre-departure document review; an initial meeting with principal stakeholders; visits to health facilities; a central-level stakeholder workshop; key informant interviews; and a validation meeting to present the findings, recommendations and receive feedback.

MAIN RECOMMENDATIONS¹

- Implement the consensus policy position and direction to move CMS from a GOM Treasury unit to an independent trust. Further studies examining the obstacles and benefits to such a move and a strategic plan outlining the necessary steps are unnecessary. They have been conducted (**Section 4.0: Policy and Organizational Context**).
- Dissolve or revise the current Medical Supplies Technical Working Group and replace it with a formal MOH department or directorate charged with oversight of all pharmaceutical services in the country and public, donor, and NGO sector PSM initiatives in Malawi (**Section 4.0: Policy and Organizational Context**).
- Link the EHP service commodities to CMS and vertical program procurement to ensure that commodity forecasting and purchasing are consistent with the EHP and SWAp objectives (**Section 4.0: Policy and Organizational Context**).
- Increase the amount DHOs and hospitals can spend on private sector commodity purchases from 30 percent of their total drug budget to 60 percent until the stock status of essential medicines and consumables for EHP services at RMS rise to levels adequate for routine resupply (**Section 5.0: Financing**).
- Select a private sector third party agent to (1) conduct ART procurement, and (2) work with CMS to build the requisite procurement management and technical capacity for a range of ART products and essential medicines (**Section 6.0: Procurement**).
- Maintain UNICEF ART procurement and distribution services for products quantified in March 2009 and distributed through October 2009 (**Section 6.0: Procurement**).
- Decrease lead times within the ART and CMS-managed essential medicines system (**Section 6.0: Procurement**).
- Make ARV distribution to the ART centers quarterly and use data from quarterly supervision visits to improve responsiveness of the distribution (**Section 7.0: Warehousing and Inventory Control**).
- Increase and formalize use of central-level storage for ARVs (**Section 7.0: Warehousing and Inventory Control**).
- Develop a communication policy and tools for the HIV/AIDS Unit to communicate with the ART sites to improve delivery schedules (**Section 8.0: Distribution**).
- Shift technical oversight of the current ART private sector distribution contract from a future third party agent to the CMS in 2010 (**Section 8.0: Distribution**).
- Introduce *PipeLine* software or other appropriate pipeline monitoring and procurement planning tool into the HIV/AIDS Unit for tracking ARV shipments (**Section 9.0: LMIS**).

¹ These and additional recommendations are detailed in the body of the report.

- Support rollout of a unified solution for computerization at dispensing windows. Replace the ARV register where possible and incorporate an inventory module into the system (**Section 9.0: LMIS**).
- Review and revise assumptions of the ARV forecasting methodology (**Section 10.0: Forecasting and Quantification**).
- Coordinate ARV forecasting with the proposed CMS quantification team structure (**Section 10.0: Forecasting and Quantification**).

The Technical Working Group for Medicines and the Health and HIV SWAp pool partners working together will need to determine which recommendations among those listed in this report they will accept. Subsequently, the implementation timeline (Section 11.3.1) for the recommendations is a critical first step toward the development of a work plan. This level of detail cannot be developed until the recommendations have been discussed, accepted, rejected, or revised. Each recommendation will require a commitment to a series of specific steps addressing the gaps identified in the “Findings and Observations” and “Rationale” sections of each chapter.

The suggested timeframe for the implementation of the recommendations is from 2nd half of 2008 2010. Given the urgency of maintaining the quality of service for the ART program and improving the capacity of the CMS essential drug system and the ART program, the team concluded that action should be focused on near-term (two to three years) improvements. Beyond that period, immediate steps recommended may become somewhat generalized and nonspecific, best suited for longer-term strategic planning. Within the implementation timeframe in each PSM category, both short-term (i.e., second half of 2008 and first half of 2009) and medium-term (second half of 2009 and 2010) recommendations have been developed by the team’s estimation of what both should and can be accomplished during this time period.

I.0 INTRODUCTION

An assessment of the ARV and integrated essential medicines logistics systems was carried out from May 19 through June 6, 2008 by a consultant team from the USAID | DELIVER Project. The purpose of the activity was to determine whether the ARV supply chain — of which several components are managed vertically to the Central Medical Stores (CMS) system — can be integrated into the CMS system without a loss of service to the more than 100,000 patients currently on ART (MMOH 2008). To make this determination, performance assessments of each system were carried out and recommendations identified to determine *if, how, and when* ARV supply chain functions can be integrated within the CMS essential medicines logistics system without a reduction in the current level of product availability and access currently provided by the ARV distribution system.

The broadest guiding principle of rapid assessment was to contribute analysis and recommendations to strengthen HIV/AIDS Commodity Security (HACS) for ARVs. Commodity security is “a situation where *patients* and *service providers* can choose, obtain, and use *medicines* and other *health commodities* when and where they need them for prevention, treatment, and care of HIV/AIDS and related illnesses.” (ZMOH 2007) Within that context, the operational principle of the assessment was to “do no harm” to the current procurement and supply chain system for ARVs. The team was careful to ensure that the recommendations in this report do not compromise the current quality of ARV access and availability to ART patients. The consultant team’s mandate also included making observations and developing recommendations for specific capacity-building measures within the CMS and MOH programs to support longer-term objectives of integrating the ARV supply chain within the CMS essential medicine supply chain. In a sense, this posed a dilemma: how to maintain (and improve) quality of service while simultaneously providing guidance to improve capacity. The recommendations in this report suggest that these two approaches are not mutually exclusive; they can happen concurrently through a comprehensive agreement, workplan, and consensus by all parties to provide resources and commit the political energy to achieving outcomes set out in the recommendations in this report.

At present, all ART program ARVs are procured and distributed by UNICEF through funding by the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). The system operates outside of but parallel to the CMS integrated essential medicines logistics system. In late 2007, the Government of Malawi (GOM) indicated that it would like to see these processes integrated and managed by the CMS system. To determine the current and potential feasibility of this position, an independent, objective assessment of CMS's capacity to manage those supply chain functions was requested by the MOH and Health Donor Group (HDG) partners.

The assessment was focused on the ARV supply chain management (SCM) components vertical to and outside of direct CMS management control (procurement, inventory control, transportation, and logistics data management); then a performance comparison was made with the corresponding CMS functions to determine current and future feasibility of integration. Additionally, other factors affecting the performance of the supply chain — human resource capacity, product and system financing, and the policy context in which these systems and functions operate — were examined.

1.1 PURPOSE AND OBJECTIVES

1.1.1 PURPOSE

The purpose of this consultancy was to determine whether the ARV supply chain, which is managed vertically to the CMS system, can be integrated into the CMS system without a loss of service. The purpose is informed and achieved by the following objectives:

1.1.2 OBJECTIVES

1. Determine which ARV logistics components should remain vertical or be integrated within CMS structures (all, none, or some) and provide rationale and data used to draw the conclusions.
2. Outline the process and specific steps which demonstrate how to optimize the ARV distribution system.
3. Provide a timeline of the actionable recommendations, including identification of accountable organizations and a suggested set of indicators to monitor performance.

MAIN FINDINGS

- This report suggests that the CMS and related public sector agencies do not currently possess adequate technical, organizational, and human resource capacity to integrate procurement, inventory control, distribution, and data collection and management of ARVs without compromising the current quality of service. As such, these functions should remain vertical to the CMS until suggested reforms have been enacted and subsequent capacity developed to carry out these procurement and supply management (PSM) functions for ARVs on behalf of the MOH's ART program.
- The findings do indicate, though, that public sector agencies (such as the HIV/AIDS Unit) are performing well with regard to logistics and patient data management, quantification of ARV consumption, and estimation of future needs. The sustainability of this function as the ART program grows is a concern. Consequently, the recommendations help chart a course that both helps maintain and improve quality of service of ART provision and details capacity-building measures within the CMS, the HIV/AIDS Unit, and other agencies to phase-in integration over time subject to improvements in performance measurement indicators included in this report.

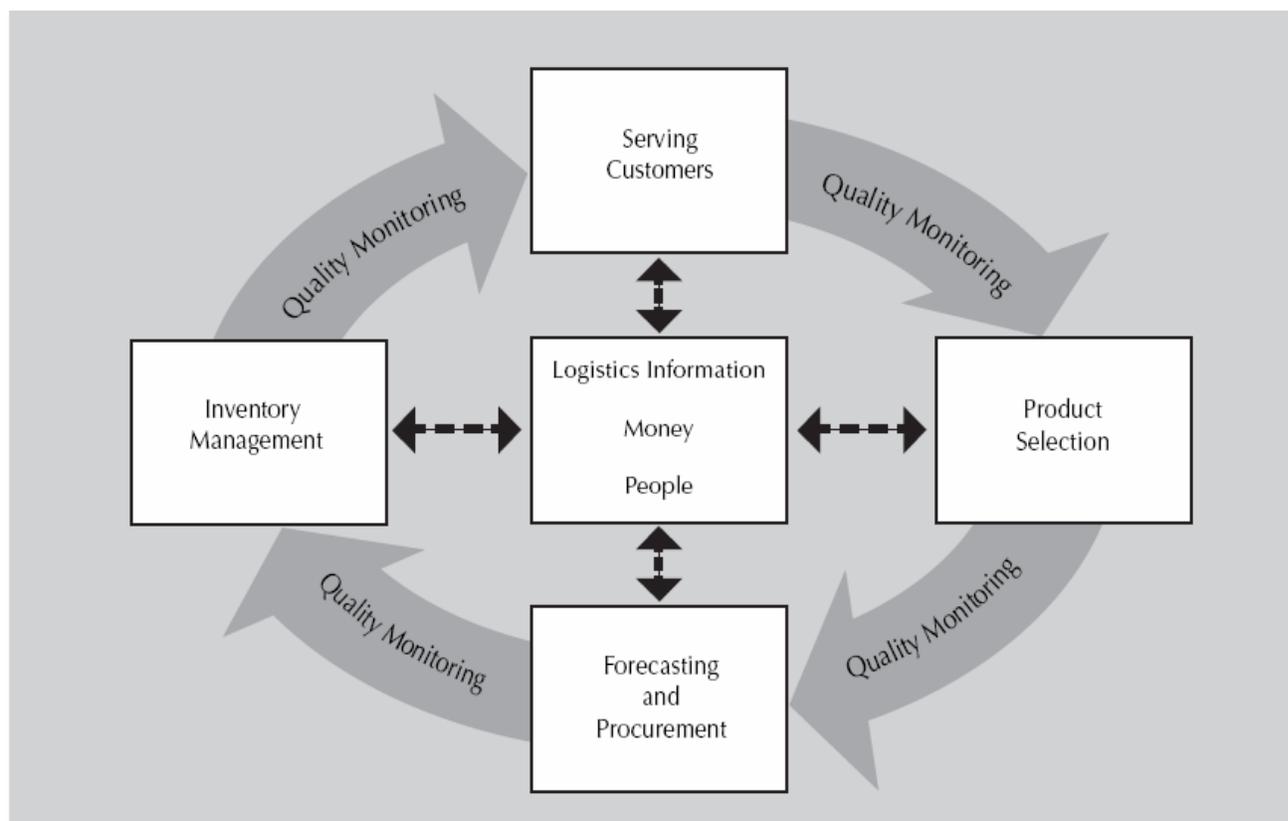
The analytical bases (e.g., information, data, and opinion) for the findings and recommendations in this report and the method from which the team expected to reach the objectives, and therefore the purpose, are the following:

- An assessment of the ARV/ART logistics system
- An assessment of the CMS essential drug logistics system

I.1.3 ANALYTICAL FRAMEWORK

This assessment was focused primarily on three supply chain functions: *procurement*, *distribution*, and *inventory control* within the ART and CMS integrated essential medicines systems. Emphasis was also placed on *LMIS* and *data collection* because these functions, although managed by the MOH's HIV/AIDS Unit, remain vertical to CMS integrated distribution system. However, the authors acknowledge that health commodity supply chain management involves a wider series of activities.

Figure I.1. ARV Logistics Cycle



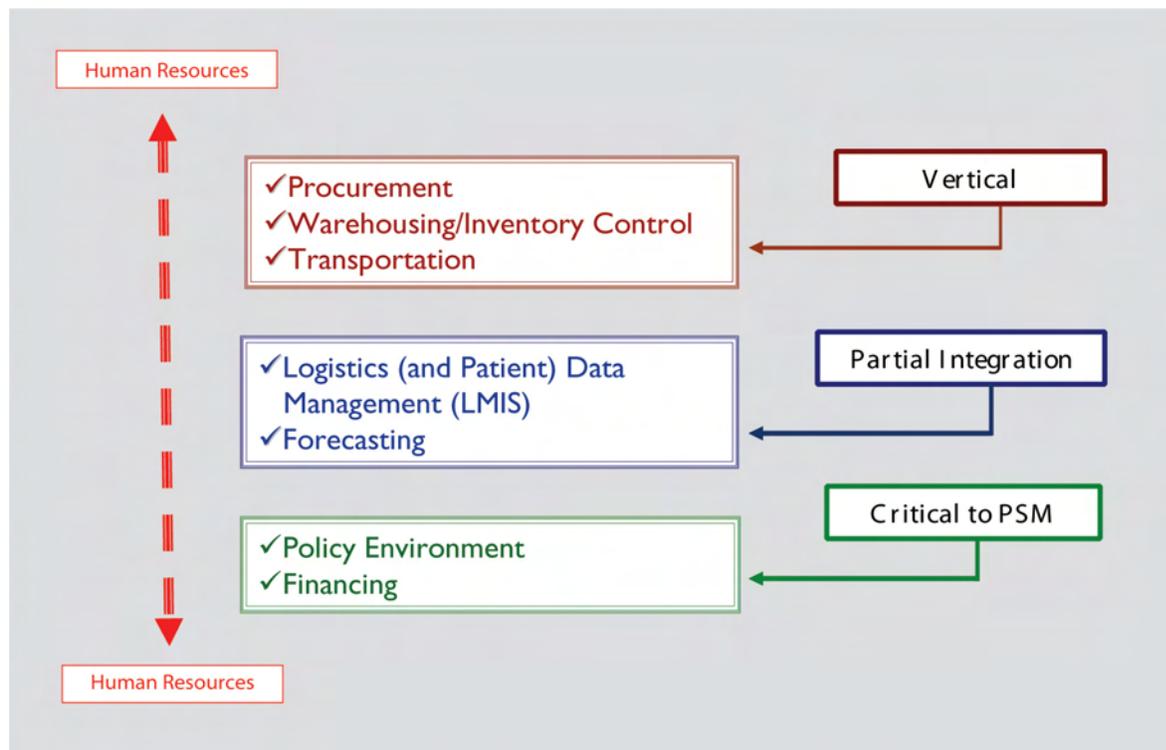
Commodity logistic systems consist of a continuous series of functions that must be routinely performed and monitored. Each function is dependent on the efficacy of the others. For example, adequate procurement quantities of ARVs can only be provided if forecasted quantities are accurate.

Determining those quantities can only be accomplished by the routine collection and analysis of consumption, health statistics (e.g., number of patients), or demographic data by skilled staff operating a management information system. The appropriate product (e.g., strength, formulary, and presentation) must also be selected and registered for use in-country as part of the logistics cycle.

Commodities must also be cleared through customs (often by a freight forwarder or customs agent at the port of entry) and undergo quality testing. For products in the in-country supply pipeline, decisions must be made regarding the number of storage and distribution tiers to ensure that products get to customers quickly and to reduce storage costs. It is also critical that logistics information reach those charged with inventory control and data management so they can make informed decisions about how much to procure from suppliers and what amounts to supply to facilities. These functions are illustrated in Figure 1.1. Vertical supply chains are often viewed as more effective because they manage a limited number of products, such as ARVs and drugs for opportunistic infections (OIs); they often use third party agents specializing in procurement and transportation; and they receive substantial funding from external donors (DELIVER 2006). They are also more costly. Health sector reform policies and a broader systems view of health sector generally support the reduction of vertical systems in favor of an efficient, integrated structure that is capable of handling all essential health commodities. However, integrated supply systems are only possible when infrastructure, capacity, and skilled human resources are available to maintain the level of service to the customers.

2.0 METHODOLOGY

Figure 2.1. Assessment Priorities



The logistics system that supports ART in Malawi is not entirely vertical. Some logistics functions are managed vertically by the MOH's HIV/AIDS Unit, including logistics data capture, forecasting, quantification and distribution planning. However, the ARVs are distributed to public sector and NGO stores that are also served by the CMS. Because the purpose of the study was to assess whether the ARV supply chain could be integrated into the CMS system this analysis required, in effect, two separate but related assessments. The analysis also had to review the performances of both the upstream components (procurement and forecasting) as well as downstream supply chain components (e.g., inventory management and in-country transportation)..

As a matter of priority, data collection efforts were focused *principally* on procurement, warehousing, and transportation — ARV logistics functions managed completely outside of the MOH and CMS systems by UNICEF.

The *second* tier of focus was on LMIS and forecasting. Those functions are what the team has described as partially integrated as they are the primary responsibility of the MOH's HIV/AIDS Unit, though outside of the CMS distribution system.

The *third* area of focus was on financing and the policy environment in which the supply chains operates. These functions are both critical to PSM, but are outside the traditional systems-based

methodology in which logistics assessments are usually carried out. Nonetheless, because each is connected to the other the methodology was designed to ensure the team obtained the breadth and depth to make informed recommendations. Observations on human resource strengths and weaknesses were documented within each section and are reflected in the recommendations.

2.1 ASSESSMENT TOOLS

The following tools were adapted to support data collection:

- The Logistics System Assessment Tool (LSAT)
This questionnaire was used primarily for qualitative data collection at the central and regional levels. The LSAT questions emphasize procurement capacity and performance, in addition to human resources, organizational capacity, financing, coordination and central-level inventory control (JSI | DELIVER 2004).
- The Logistics Information Assessment Tool (LIAT)
Originally designed to measure performance for family planning products, the LIAT was recently adapted for use with ART programs. The tool was used to obtain quantitative data on storage facilities and service delivery points (USAID | DELIVER 2007).
- The HIV/AIDS Commodity Assessment (HACS) Questionnaire (Draft)
The HACS Tool is designed to collect information on the broad set of systems, programs, functions, and policies that make up the inputs for routine product availability (financing, policies, and human resources in the health sector, regulations/laws and coordination). Select questions from the HACS tool were applied in certain areas to augment questions absent in the LSAT and LIAT.²

Each of the tools (questionnaires) contained several hundred questions designed to help the team obtain the necessary qualitative and quantitative data — and opinion — needed to inform the objectives and, hence, answer the main study questions.

2.2 DATA COLLECTION METHODS AND VALIDATION

2.2.1. Pre-departure Document Review

The DELIVER field office and the consultants identified and reviewed several reference documents which evaluated CMS performance, procurement issues in the country, and regulations and policies on essential medicines. Very little documentation had been reviewed regarding ARV distribution prior to arrival in-country. Additional information regarding the UNICEF procurement and transport contracting system, for example, and ARV data collection and forecasting methodology was obtained through interviews and document collection in-country. The purpose of this step was to provide context and familiarity with previous efforts, ongoing reforms, and existing strategies, and the positions of the various stakeholders. The team was keenly aware that previous recommendations on the subject matter had been made and was careful not to duplicate efforts.

² This is a draft questionnaire used to conduct a commodity security assessment in Zambia. It is unpublished but available from the authors.

2.2.2. Initial Meeting with Key Stakeholders

The consultants met with staff from the DELIVER field office, USAID/Malawi, and CMS to discuss the objectives and methodology prior to the initial stakeholders' meeting and facility visits. It was also an opportunity to plan follow-up meetings in the first and third weeks of the assessment.

2.2.3. Facility Visits

The DELIVER field office, working with the MOH, CMS, and the HIV/AIDS Unit identified appropriate ART sites and warehouse personnel to interview and obtain data. The facility visits were originally planned for the second week of the assessment, following the Key Informant Workshop. But because a number of stakeholders from the MOH were out of the country during the first week, the team proceeded with the facility visits. In hindsight, this was fortunate, as it enabled the team to share health facility staff input with Lilongwe-based staff and contributed to a more in-depth discussion of the key challenges in the Central Level Group Workshop (Section 2.2.4. below).

The team split field visits, traveling with counterparts from the JSI Malawi office, with one group visiting the Southern region and the other the Central region. Time and staff did not permit visits to the Northern region. The purpose of the field visits was two-fold: first, to collect baseline data on the current distribution performance of the two systems (ARVs and CMS integrated essential medicines); and second, to identify any concerns and/or support at the regional and service delivery levels associated with the potential integration of the ARV/ART distribution system within CMS. The field visits also served as an opportunity to use the tables from the ARV LIAT to collect quantitative stock data for tracer products from service delivery points, DHO stores, and the RMS.

Table 2.1 indicates the number, location, and type of facility visited by the team. The list includes two of the three RMSs, the main public hospital in Lilongwe (Kamazu Central Hospital), and a number of NGO and public sector ART facilities in the Central and Southern regions.

Table 2.1. Facility Visits

FACILITY-BASED VISITS			
Name (n = 13)	Organization	Location	Position
(Dispensing Nurse)	District Hospital ART Facility	Dedza	Dispensing Nurse
(Pharmacist)	District Hospital Pharmacy	Dedza	Pharmacist
Billy Mwapasa	Southern Region RMS	Blantyre	Pharmacist-in-Charge
Dan Chunda	B'Vumbwe HC	Thyolo	Medical Assistant-in-Charge
Hastings Chiumba	DHO	Dedza	Director
Irene Mugombo	Ndirande ART Center	Blantyre	Nurse
Jean Maloga	Ndirande ART Center	Blantyre	Medical Assistant-in-Charge
Mary Kaputa	Kaphuka ART Facility	Dedza (District)	Nurse-in-Charge
Mr. P.G. Singini	Blantyre DHO	Blantyre	Pharmacy Technician
Mrs. Stella Sipanga	St. Joseph's Hospital	Blantyre	ART Center In-Charge
Ralf Weigel	Lighthouse Clinic	Lilongwe	Clinical Advisor
Reuben Banda	Southern Region RMS	Blantyre	Regional Logistics Officer
Rose Chikumbe	Kamazu Central Hospital	Lilongwe	Chief Pharmacist

2.2.4. Central-Level Workshop

The team organized a one-day workshop in Lilongwe in the second week of the visit, following the facility visits. Participants included USAID, CMS, the Deputy Director of the Directorate of Health, Technical Support Services (DHTSS), UNICEF, the Clinton Foundation HIV/AIDS Initiative (CHAI), and several others.

The purposes of the meeting were (1) to present the proposed rationale and methodology of the assessment(s); (2) to receive feedback from key informants on the methodology; (3) to obtain input on the priority SCM technical areas/gaps/strengths of each system; and (4) to establish contacts with technical and policy stakeholders for follow-up interviews and data provision. The proceedings were documented and helped the team prioritize the analysis and identify additional documentation. During the second half of the day the participants were divided into working groups to identify key PSM issues for each supply chain the team was examining (see Agenda, Annex 1).

During the various steps in the methodology, the team actively transcribed interview notes, discussed inconsistencies between the data and information obtained during interviews, and began to draw preliminary written conclusions about the performance of each system and recommendations regarding whether and how integration of the ARV supply chain should proceed. This analysis formed the basis of the presentation made at the validation meeting and is detailed in the following sections of this report.

2.2.5. Key Informant Interviews

Following the workshop, additional key informant interviews took place during the second and third weeks of the assessment. The team used questions adapted from the supply chain tools discussed earlier as a guide to help understand the facts and opinions, and also as an opportunity to collect quantitative data where available. (The full list of those interviewed is presented in Annex 2.)

2.2.6. Validation Meeting

Stakeholders were invited back to a validation meeting on the final day of the visit, Friday, June 6, 2008. The team presented its findings and recommendations for discussion to validate and/or refine the recommendations and confirm the engagement of key stakeholders in the proposed implementation process. Input and participation was greater than expected. A planned three-hour meeting resulted in a five-hour discussion of the findings and recommendations, with consensus that a workplan should be developed to detail the recommendations adopted by the MOH and health donor partners.

3.0 VIEW OF THE CURRENT SUPPLY CHAINS

3.1 FINDINGS AND OBSERVATIONS

Essential medicines managed by the CMS and antiretroviral medicines for the ART centers are managed in completely different ways. They have different sources of funding, different procurement agents, different customs clearance agents, and are stored centrally in different locations. ARV allocation and distribution plans are made by the HIV/AIDS Unit of the MOH semi-annually, using patient data which is collected quarterly, whereas the job of the CMS/RMS system for the public sector is to respond to monthly medicine requisitions from District Health Offices that use logistics data reported monthly.

The two sets of products are transported by different agencies using different vehicles over different routes to reach the hospitals and health centers. At the hospital and health center level, the ART center usually has at least one staff member dedicated full-time to the program. In lower-level tiers, clinical responsibilities are spread across all programs. The only point at which these supply chains converge is at the physical location of the health center itself. In effect, as of June 2008, these supply chains have nothing to do with one another on a day-to-day operational level.

3.1.1 ARV SUPPLIES MANAGEMENT

As of the end of December 2007, ARVs are supplied to 118 public health facilities and 45 private sector/NGO facilities (MOH Malawi 2008). By design, distributions are supposed to occur on a semi-annual basis from the SDV Malawi Limited (the private sector firm contracted by UNICEF to

Although ARV orders may be placed semi-annually with suppliers by UNICEF, SDV receives those orders in the form of roughly 40 independent shipments over the course of the year.

distribute ART products) warehouse in Lilongwe, transported straight to the ART centers. However, discussions with SDV revealed that some ART centers are receiving three distributions per year. The additional distribution may be related to high volumes or the need to distribute less generally used,

second-line therapies that cannot always be bundled with the first-line therapies that comprise more than 90 percent of the current treatments. One facility visited in the Southern region, St. Joseph's Hospital, had only received one distribution in the beginning of 2007. This was confirmed by reviewing their stock cards. Since they did not stockout of Triomune, it is probable that the volume of dispensing simply did not require a second distribution during the period. A second site, Ndirande, reported receiving medicines on a quarterly basis but this could not be confirmed against records. Some variation compared with the distribution policy is not surprising, and this was a small convenience sample so the observations are not necessarily typical. Further, although UNICEF may

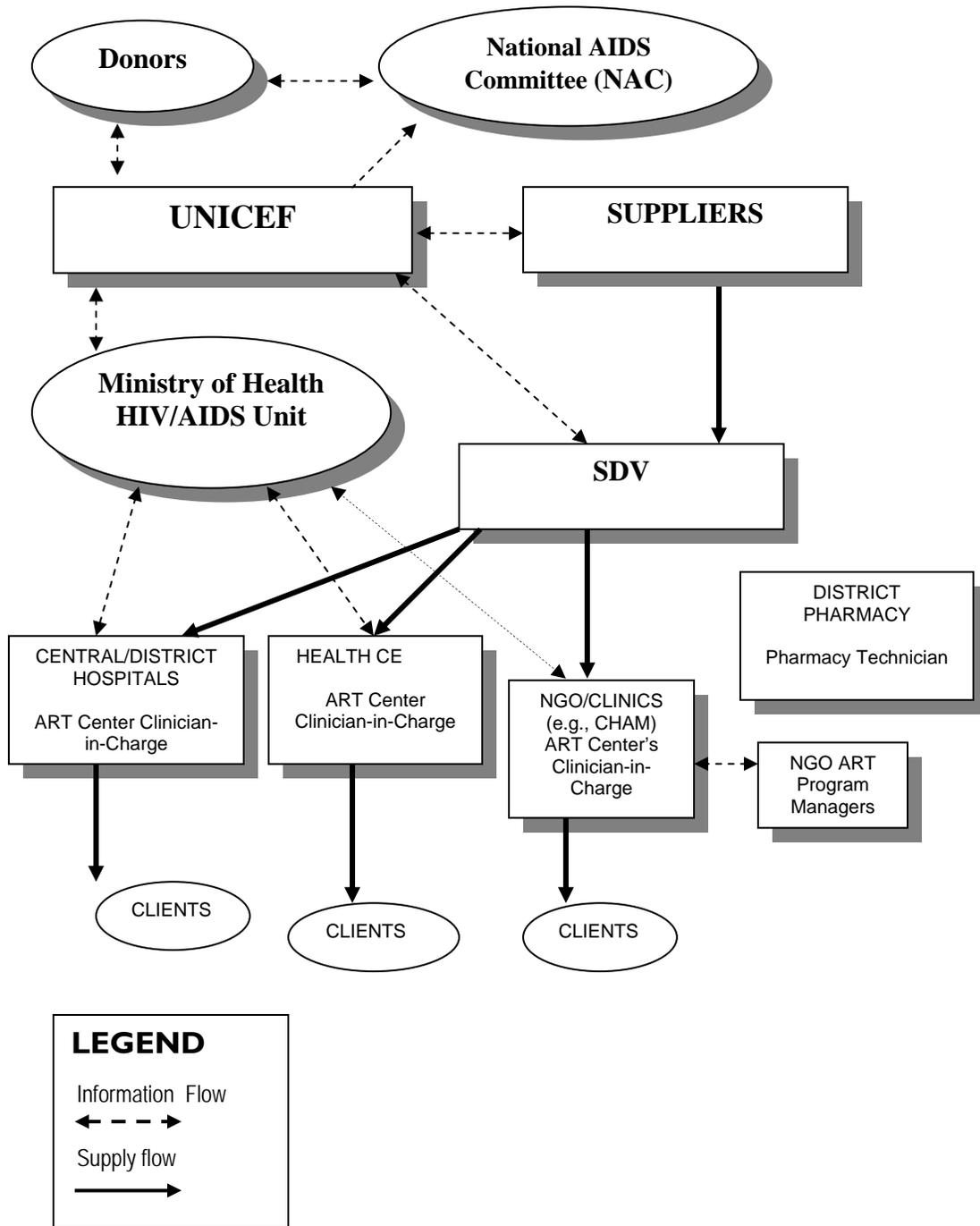
place ARV orders semi-annually with suppliers, SDV receives those orders in the form of roughly 40 independent shipments over the course of the year.

In principle, all distribution is managed by SDV based on a distribution plan provided to them by UNICEF, originating with the HIV/AIDS Unit. SDV then uses its own vehicles or leased vehicles to distribute goods to the ART centers. Again, SDV mentioned that there are some exceptions. During the rainy season, for example, some ART centers may have to send their own four-wheel-drive vehicles to pick up medicines. Also, some of the NGOs receive ARVs on behalf of their ART centers and then distribute to their hospitals and health centers using their own transportation resources. These are exceptions that SDV has to manage.

According to SDV, in practice, it takes about five to six weeks from the time ARVs arrive in SDV warehouses until the ART center allocations are complete. Variability occurs because UNICEF must supply SDV with a release note and a distribution plan, which may take one to two weeks from time of receipt. Subsequently, break-bulk packing of ART center semi-annual allocations and physical distribution to the 163 ART centers routinely takes four weeks. *In principle, goods pass through SDV and there is no planned inventory holding in their stores. In practice, this is not the case.*

SDV provides the physical management but the HIV/AIDS Unit is the hub of all of the supply planning activity. In principle, teams under the direction of the HIV/AIDS Unit travel quarterly to all 163 ART centers to extract the necessary data, both for health indicator reporting and logistics decision making. In this way they do not have to depend on facilities reporting to ensure timely, accurate data. Inventory levels at the ART centers are meant to be between two and eight months of stock, and no recent stockouts of ARVs were reported by any of the facilities visited (although the same could not be said for OI drugs). The distribution plans prepared by the HIV/AIDS Unit, based on complete and routine data, have been highly effective in responding to patient requirements at the ART centers. This task is becoming more difficult to manage as lead times have increased (see Procurement, Section 6.0) and more patients switch to alternate first-line and second-line regimens.

Figure 3.1. Movement of ARV Commodities and Data



3.1.2 CMS SUPPLY SYSTEM

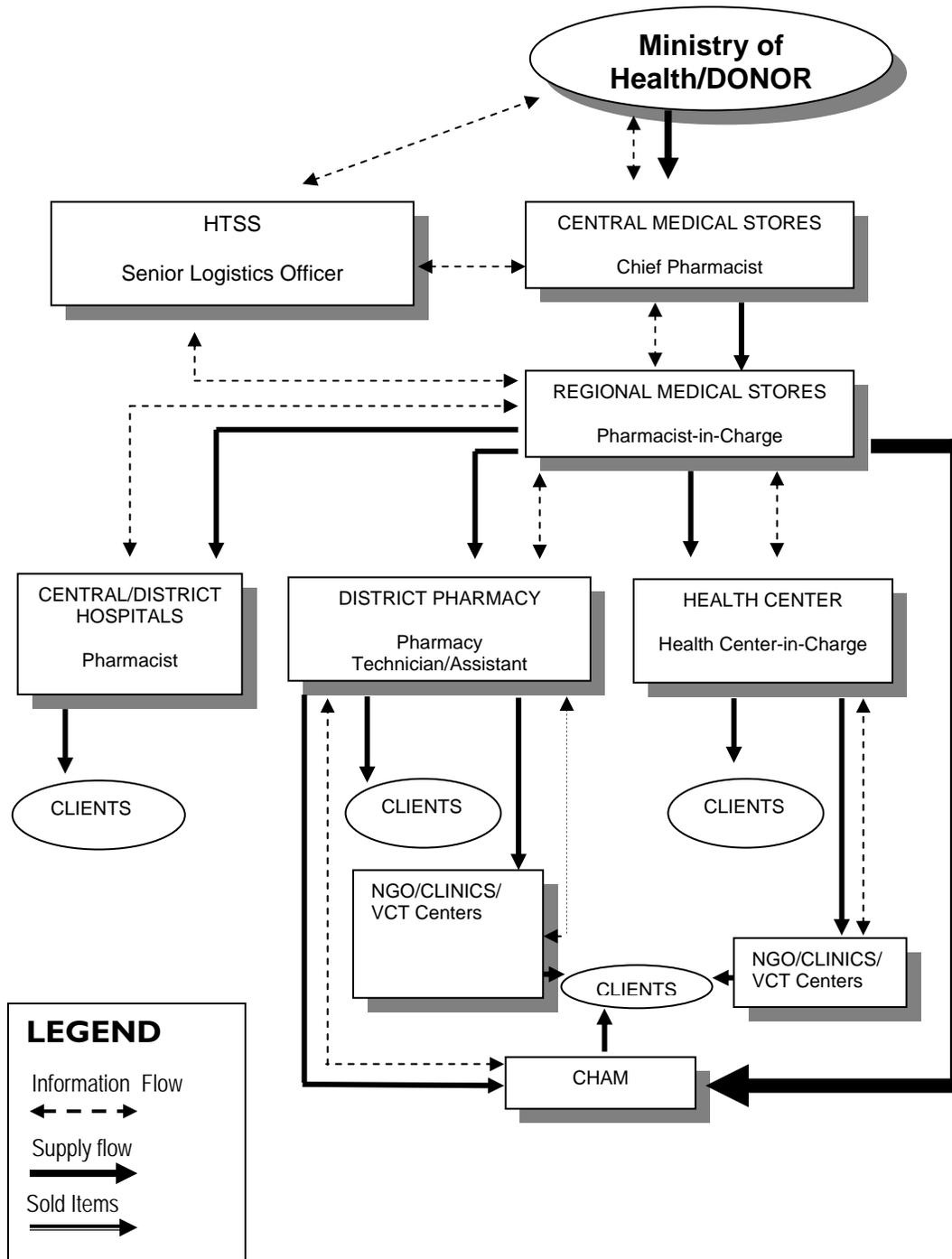
The CMS supply system supports the distribution of more than 2,000 different medicines, equipment and non-drug consumables to roughly 366 government public health centers in 27 districts, 30 hospitals, and more than 150 Christian Health Association of Malawi (CHAM) health centers and other NGO centers. The CMS manages donated products which must be distributed free to public and private service delivery points. Products it procures and distributes to government health centers are billed to District Health Offices (DHOs) and NGO facilities. The movement of commodities in their system is correspondingly more complex and fraught with opportunities for breakdowns. Goods entering this system pass through the CMS Receipts Section under the management of the Chief Pharmacist. Goods are then allocated or “pushed” to the three Regional Medical Stores (RMSs) to enable them to respond to monthly requisitions from the DHOs. In principle, the RMSs then use their own vehicles to distribute the goods to health centers based on district requisitions prepared by the District Pharmacy Technician and the availability of the goods at the RMSs. District hospitals, because they are their own cost centers, requisition their requirements directly.

According to recent proposals, the CMS/RMS is to hold between six and twelve months of stock and the health centers hold between two and three months of stock. Practically speaking, the CMS/RMS warehouses have insufficient space to hold such a level of central inventory. Nor does the CMS have the budget to procure goods up to these levels for all of the goods it is required to manage. Inventory levels in the RMSs vary widely, with some goods such as plaster of paris (PoP) bandages, digoxin tablets and transfusion sets being seriously overstocked (>two-year supply), and other products such as HIV test kits stocking out for up to one month.

Issues to health centers by the CMS/RMS are based on data reported by the health centers to the district. These data are seldom complete for every health center and, within districts, not all health centers report regularly. Nevertheless, districts have the tools necessary to prepare credible requisitions for at least the reporting facilities. Unfortunately, these same data are not sufficiently complete for CMS procurement planning. In one hospital where fill rate is being monitored, the CMS/RMS response is a dismal 50 percent of SKUs requisitioned.

Even with its performance flaws, the CMS/RMS system has some advantages, including a simple design with clear, well-documented reordering rules; a short lead time (one to two weeks for in-stock products) and review period (one month); routine delivery schedules; and, as of this year, monthly supervision to the districts. By decentralizing storage to the regions, CMS has put the inventory closer to the final customers. One of the main weaknesses of the CMS decentralization is that the basis of the supply allocation to the regional stores is a simplistic, population-based allocation used across all products which ignores the available historical consumption data.

Figure 3.2. Movement of Health Commodities and Data (CMS) ^{3,4}



³ Central Medical Stores sells drugs and other health commodities to hospitals belonging to CHAM and other private organizations. These items are not tracked through the Malawi Health Logistics Management System. The only health items this system tracks in CHAM, NGO and private organizations are those that are donated to the GOM through MOH and come in different programs such as the Sexual and Reproductive Health Program.

⁴ Recommendations will be provided in the “Warehousing and Inventory Control” and “Distribution” sections, respectively.

4.0 POLICY AND ORGANIZATIONAL CONTEXT

4.1 INTRODUCTION

Malawi is largely dependent on donor contributions to maintain public sector services. It is estimated that donors contributed approximately 40 percent to Malawi's annual public sector budget. The main donors are the (British) Department for International Development (DfID), the European Union (EU), the World Bank, GFATM, the United Nations Children's Fund (UNICEF), the U.S. Agency for International Development (USAID), and others. Donors in Malawi are increasingly harmonizing development assistance through sector wide approaches (SWAs) in health, agriculture, and other sectors, and through direct budget support to the GOM. Budget support is also provided through the Common Approach to Budget Support (CABS) group. The GOM is increasingly taking the lead in coordinating donor support. As part of the Millennium Development Goals (MGDs) process, the GOM has developed a Development Assistance Strategy (DAS), which is aimed at improving the effectiveness of aid inflows to Malawi and defining what the GOM and its development partners must do to implement the Paris Declaration on Aid Effectiveness, which was signed in March 2005 (World Bank 2008).

4.2 FINDINGS AND OBSERVATIONS

The GOM has finalized a six-year Program of Work (POW) for the Health Sector (2004–2010). The POW has been implemented at the national and district levels since October 2004, with financial and technical support from the GOM and its development partners. The Health and HIV⁵ SWAp provides a common framework for health sector planning, budgeting, financing, financial management, and reporting and monitoring and evaluation, as well as agreement on both yearly and mid-term reviews. The donor share of actual net funding has gradually increased from 30 percent in 2004–2005 to 56 percent in 2006–2007 (SWAp 2007)⁶.

Malawi has seen slow progress in development over the past 15 years. Donors feel they have put in a tremendous amount of resources over the past decades and have not seen the desired operational improvements in government health structures, financing, and HR capacity, nor in many of the hoped for health outcomes.

⁵ The World Bank is leading efforts to develop a parallel SWAp to the Health Sector SWAp for HIV programming only. The team was unable to obtain further information on these efforts.

⁶ See Table 5.1

LINK BETWEEN THE EHP AND PRIORITY HEALTH COMMODITIES IN THE SUPPLY CHAIN

The basis of the SWAp is to ensure the availability of the Essential Health Package (EHP), which is a minimum package of health services provided free of charge at service delivery points (SDPs) to all Malawians. Essential Health Package components include those for routine immunization, diarrhea and cholera prevention, HIV, tuberculosis, malaria, reproductive health, and a range of acute infections. Medicines for these services are provided by the CMS procurement and distribution system and a range of vertical and partially integrated programs managed by UNICEF, USAID, the Clinton Foundation HIV/AIDS Initiative and numerous NGOs. However, there has been little progress made in aligning the medicines needed to treat conditions in the EHP with a corresponding list of vital tracer products within the CMS distribution system or among other health partners. Instead, essential medicines have been defined in various, disjointed ways according to anticipated demand from DHOs and product demand fulfilment mandates of specific vertical programs. Many of these health products address EHP services but not in a coherent, coordinated approach.

...there has been little progress made in aligning the medicines needed to treat conditions in the EHP with a corresponding list of vital tracer products within the CMS distribution system...

The SWAp “Mid-Term Review” published in November 2007 found additional significant deficiencies in several aspects of supply chain systems managed by the CMS, including long lead times, stockouts of essential medicines to support the

EHP, and absence of consumption data to make accurate demand forecasts. The ART program, however, has been proven effective at supplying Malawians with the products they need for effective treatment, even though the program is highly verticalized, with procurement, storage, and distribution managed by UNICEF and private transport contractors. Within this context, the Health Donor Group and many MOH organizations concluded that an assessment of the ART system and the CMS essential medicines distribution system was “long overdue” and a roadmap for CMS/MOH to begin a transition to integrate the ART system fully within the CMS was needed.

Many key informants within the CMS and other units suggested that the MOH policy decision to support the near-term integration of ART procurement and distribution within the CMS system was premature. The decision should not have been made before a comprehensive assessment was conducted that would indicate current strengths and challenges within the CMS and point out specific steps to strengthen the system so it could support ART SCM functions. However, they indicated that the GOM is truly concerned with strengthening the capacity gaps up and down the supply chain, especially in drug procurement.

4.2.1 ARV Supply Policy Context

During 2003–2004, ART in the public sector was just getting ramped up in Malawi. Previous to this period there were approximately 4,000 patients on ART in the public sector. By the end of 2004, there were more than 13,000 patients on ART, and in January 2008 nearly 150,000 patients had started ART therapy (MOH 2005; MOH 2008).

Based on a PSM assessment of the Malawi health sector, a decision was made in late 2003 – early 2004 to use UNICEF as the procurement agent, as an interim step while the CMS procurement and distribution networks increased capacity to manage ARV distribution.

The rapid scale-up was due both to the GOM’s commitment to put people on treatment and the

involvement of the GFATM to provide treatment and prevention supplies, and, in agreement with GOM, build procurement and supply chain capacity. Based on a PSM assessment of the Malawi health sector, a decision was made in late 2003 – early 2004 to use UNICEF as the procurement agent, as an interim step while the CMS procurement and distribution networks increased capacity to manage ARV distribution. At that time, UNICEF also contracted out the trans-shipment storage and health center distribution to SDV International Logistics, a European-based freight forwarder and transport service provider (MMOH 2008).

There is a **Memorandum of Understanding (MOU)** between NAC/MOH and UNICEF that states UNICEF will conduct procurement and distribution of ARVs. The MOU does not have an end date but there is general consensus within UNICEF and among all partners in the country that the arrangement not be viewed as permanent. UNICEF, acting on behalf of the principal recipient (PR) and GFATM, is “filling the void” until it is judged that adequate capacity exists within the CMS to procure and distribute ARVs.

Capacity-building within the CMS for the procurement and distribution of ARVs — since efforts began in 2004 — has been ineffectual (according to UNICEF) because:

- CMS cannot maintain a cadre of staff with expertise in procurement and supply management.
- Staff maintenance is traced back to the nature of CMS as a Treasury organization, dependent on seconded staff from various departments.
- There is lack of political will and budgeting priorities to improve capacity.

Nonetheless, UNICEF states categorically that their role should not permanently replace government functions. But the support for GOM to conduct PSM and their current capacity presents a dilemma when trying to deliver quality ART services. If UNICEF or a similar partner does not step in to manage the functions, then the program will suffer without improvements in CMS capacity. UNICEF has agreed to stay in their as long as the partners want them so as to ensure that the ARVs are procured and distributed effectively.

4.2.2 CMS Supply Policy Context

Under the new Health SWAp initiated in 2004, the GOM and its collaborating partners have committed to reform the procurement and distribution of drugs and medical supplies in Malawi. Improving the performance and accountability of CMS is central to this task. The MOU between the GOM and its collaborating partners concerning the Health SWAp recognizes that efficient reforms of the drug and supply system are necessary to improve access to drugs as well as improve confidence in the effectiveness and integrity of medical supplies procurement and distribution among the collaborating partners and the public. The MOU commits the GOM and its collaborating partners to improve stock management controls, retain adequate and competent staff, strengthen accountability mechanisms, and strengthen management capabilities at CMS, district and local levels (Glocoms 2007).

GOM contracted with Glocoms, Inc. to function as an external management agent to strengthen CMS performance across its core functions and improve accountability, as well as review and present options for transforming CMS into an independent trust under MOH guidance. This process was not successful.

Subsequently, the GOM contracted with Glocoms, Inc. to function as an external management agent to strengthen CMS performance across its core functions and improve accountability, as well as review and present options for transforming CMS into an independent trust under MOH guidance. Glocoms's efforts to improve CMS performance and support the transition to a trust were not successful. Glocoms's support was provided by DfID, through the SWAp basket mechanism. However, for reasons unknown to the assessment team, their contract was not renewed after less than two years of managing CMS procurement efforts. As a result, the capacity of CMS to carry out international and national procurements, manage inventory, and respond to requisitions from the DHOs continues to be severely constrained. To its credit, Glocoms did put forward to the SWAp group and CMS a strategic business plan and reforms proposal to turn CMS into an independent trust to address the ongoing human resource and skills shortage at CMS and allow it to become more accountable for its performance. However, the coordination and political leadership needed to implement these reform proposal and business plan have been absent at the Drug and Medical Supplies Technical Working Group (TWG) and MOH agency responsible for CMS oversight — the Health Technical Services and Support (HTSS) Pharmaceutical Unit.

4.2.3 Policy Support for CMS as a Trust

The process to transform CMS from a unit of the GOM Treasury to an independent trust, accountable to both a board of directors and the GOM, began as early as 1992. Following years of inactivity, Glocoms, Inc. proposed a reform initiative that laid out the benefits and challenges of a trust in a draft strategic plan (2003–2006) and an additional CMS Strategic Plan (2006–2011) (Glocoms 2007). An additional set of consultant visits and reports financed by DfID reinforced the decision to transition the CMS to an independent trust and detailed the process in which this could happen, as well as the benefits and challenges. Finally, in 2006, a high-level steering committee was formed, which is chaired by the Permanent Secretary for Health and includes senior staff from HTSS, the Ministry of Finance (MOF), health partners, and the director of CMS. Despite the policy support evidenced in these concurrent and overlapping efforts to transition CMS to a trust, the transition process has failed to demonstrate progress, in part due to lack of political commitment to provide initial funds to capitalize the reorganization and the absence of political will on the part of the GOM to address the myriad legal and regulatory challenges associated with the transition. In the view of this consultant team, the principal benefit of a trust is that it would enable the CMS to assert more control and accountability over PSM staff within the organization and be in a position to provide incentives to those staff to remain at the institution and use their expertise to grow the capacity of CMS to perform its core technical functions.

Without addressing the human resource turnover rate within the CMS system, efforts to build capacity among staff will be a costly enterprise that will yield little dividend. A shift to a trust or similar autonomous central supply agency can address the issue by providing the organizational context in which to retain and build skills necessary for the long-term viability of CMS. Alternative structures may also be suitable. However, there is consensus and policy support within the MOH and among other Health SWAp partners to move forward immediately with the steps needed to transform CMS into a trust.

4.3 RECOMMENDATIONS

- 1. Dissolve or revise the current Medical Supplies Technical Working Group and replace it with a formal MOH department or directorate charged with oversight of all pharmaceutical services in the country and public, donor, and NGO sector PSM initiatives in Malawi.**

- **Rationale**

The current organizational framework for making progress on service performance on procurement and supply management (PSM) of essential medicines, including HIV/AIDS, has been ineffective. There have been several earnest attempts by the GOM and health donor partners to identify a framework for PSM activities and execute them accordingly to build capacity and improve PSM service for upstream (e.g., procurement and forecasting) and downstream (e.g., data collection and storage) logistics activities. GOM leadership in this area is diffuse and lacks coordination and active management. A revamped and/or new permanent department or directorate charged with the portfolio of PSM activities should be led by a senior Malawian official with knowledge of and expertise in drug management and logistics, who would report to the Permanent Secretary for Health.

This organization should be an officially designated, high-level office within the MOH, and composed of a small cadre of senior Malawian technical experts reporting to a newly created post of Director, Procurement and Supplies Management. This group, with guidance and support by the broader PSM/TWG (composed of GOM and health partner staff) would propose policies and practices for PSM functions across all the programs and ensure that they are implemented. It would use the authority of the office of the Permanent Secretary for Health and support of health partners to ensure funding and implementation of workplans for PSM capacity-building; adopt policy decisions on verticalizing or integrating supply chains; and source/coordinate technical assistance efforts to improve CMS ability to provide customer service at SDPs. [See draft Terms of Reference (TOR) in Annex 3.]⁷

Examples from Kenya and Tanzania

In 2000, Kenya moved toward transforming its central and regional medical supply stores into a parastatal organization: Kenya Medical Supplies Agency (KEMSA). Other governments are divesting themselves of parastatals altogether and replacing them with autonomous authorities or boards that function largely on commercial principles. One example is the Medical Stores Department (MSD) in Tanzania, formed in 1993.

Parastatals were theoretically designed to maximize financial revenues for government treasuries. Autonomous Supply Agencies (ASAs), although similar in structure to parastatals, are independent, not-for-profit organizations. Both types of purchasing agencies usually operate a Revolving Drug Fund (RDF) and manage donor funds for procurement, which may include certain importation clauses, such as exemption from duties and taxes (Rao et al. 2006).

2. Implement the consensus policy position and direction to move CMS from a GOM Treasury unit to an independent trust. Further studies examining the obstacles and benefits to such a move and a strategic plan outlining the necessary steps are unnecessary; they have been conducted. This will, at minimum, require political commitment by the GOM and health partners to:

1. Provide substantial capitalization from GOM and SWAp accounts for operations and funding for product procurement in the first few years of operations.

⁷ The materials and model are from Zambia's Drug Supply Budget Line (DSBL) Office in a presentation given by Dr. Bonface Fundafunda, Manager, DSBL, MOH/Zambia.

2. Provide more limited funding for operations and recapitalization of the CMS procurement fund from GOM and SWAp accounts, as revenue increases from the sale of medicines to DHOs.

- **Rationale**

The CMS staff is made up of several different public sector organizations, including the MOH, MOF, and Common Service staff. The CMS, as an institution, does not have authority over assignments of these staff. As a consequence, organizational rotations, promotions, and attrition rates of CMS staff are high. Transitioning CMS into a trust, with greater autonomy, will give the organization greater control over staffing decisions and the ability to maintain a trained and experienced cadre of personnel to carry out procurement planning and contracts management.

The move toward a trust makes sense insofar as it addresses the human resource issue at CMS. The trust would enable CMS to hire and retain staff within a defined organizational framework instead of relying on seconded staff that often leave or get promoted within their originating organizations. Apart from that, a trust might also increase accountability by giving CMS greater discretion to provide higher pay and dismiss underperforming staff.

The proposed trust would act as a central store structured similar to a semi-autonomous government agency that reports to the government and, initially, is managed by a private firm under government contract. The trust would be similar to the CMS model and would operate with a similar financing mechanism, such as what amounts to a Revolving Drug Fund (RDF), with revenues coming from sales to DHOs to cover procurement costs and a differential fee structure and different governance structures. An example of a centralized procurement trust, or Autonomous Supply Agency, is the Medical Stores Department (MSD) in Tanzania, which has its own legal framework incorporated by an act of Parliament. MSD is the major procurement, warehousing, and distribution body in Tanzania. The model was established as a way to bring strong procurement management into the public sector and satisfy the demands of stakeholders for a more effective and efficient use of public resources. Under its mandate, MSD can contract with outside agencies (NGOs) to procure on its behalf and it uses ICB procedures — conducting national competitive bids and using economies of scale to achieve competitive prices for pharmaceuticals and other health commodities. There is a risk element in the governance and accountability of these models. Good oversight structures and routine auditing, along with performance monitoring and evaluation, are minimum requirements.

3. **Seek and obtain clarity on the GOM/MOH position on integrating all ART PSM functions within the CMS.**

- **Rationale**

Countless objective studies conducted over the past 24 months have indicated that CMS capacity to carry out a number of SCM functions (particularly procurement) is inadequate for the current responsibilities with regard to the integrated essential medicines supply chain. It is not a case of complete failure. A number of functions, such as transport of product to health centers, storage, and effort on behalf of existing staff are present. However, for reasons made in clear in the previous studies — and in this report — a number of improvements must be made to CMS, in its existing form, modified, or as a trust, if Malawi is to obtain a viable drug distribution system. The added management and technical complexity of integrating ARVs and, broadly, ART products into an

overburdened institution is not feasible. The GOM policy position should consider these realities and implement PSM capacity building measures by the group outlined in Recommendation no. 1 (above).

4. **Supply chain experts and clinicians familiar with the EHP from the various integrated and vertical programs (e.g., ART, TB, malaria, PMTCT, and the CMS), along with policy makers, should assemble for multiday workshop to align product selection, procurement, and distribution decisions of health products with the EHP.**

- **Rationale**

CMS is making procurement and distribution decisions that are inconsistent (though not entirely) with the medicines needed to treat conditions set out in the EHP. EHP-based essential medicines should be designated, at a policy level, as those products that must be in full supply (routinely available) in Malawi. Current procurement practice at CMS is based on estimated demand from DHOs, not on a list of essential products necessary to treat the majority of primary disease burdens. Naturally, some correlation exists, but a logistics system that maintains robust data management and full procurement of quantities of EHP products can better support EHP objectives. The product list would amount to the “essential of the essential” medicines and consumables, and should be routinely updated to include current ART regimens, ARVs for PMTCT, and consumables and rapid test kits for voluntary counseling and testing (VCT) and reagents and consumables for laboratory services. Integration of this list within the CMS and vertical supply chains will support a *potential* transition of the ART procurement, distribution and data management function to the CMS system.

5.0 FINANCING

5.1 OVERVIEW

Malawi is a resource-poor country, ranked 165th of 177 nations on the World Development Index (WDI 2007)⁸. Gross national income (GNI) was estimated at \$3.14 billion in 2006, translating into per capita GNI of \$230.

The principal method of financing for the health sector is organized and delivered through a pooled “basket” funding mechanism, based on a common sector wide approach (SWAp). The MOH leads the SWAp process, along with the major donor partners referenced in Section 4.0. The majority of the pooled funds associated with this coordinated approach for the health sector support the MOH’s strategic approach described in multiyear Program of Work (POW). Health sector program financing is also provided by way of direct budget support to the GOM and bilateral assistance from donors that are not included in the pooled funds.

Table 5.1 provides a breakdown of SWAp budget allocations, sources, and actual expenditures from 2004–2007 (SWAp 2007).⁹

- In the three-year period, Pool Funder contributions to the basket have risen from \$8 million to \$64 million. GOM allocations have increased from \$41 million to \$55 million in the same period.
- Total SWAp basket allocations were \$123 million for the 2006–2007 period, compared with \$58 million in 2004–2005.
- Discrete partner support (donors, for example, who do not regularly allocate budget to the pool) allocated \$4 million to the SWAp account in the 2006–2007 period, amounting to 3.3 percent of the total. Several of these partners also contribute SWAp-related activities through bilateral “off-budget” programs.
- SWAp funding from all sources has increased 122 percent in the period from 2004–2007. Although quantitative figures were not available at the time of this analysis, much of the spending — according to the “Mid-Term Review” — was driven by higher essential medicine costs and volume (e.g., ART, malaria) and public sector health staff costs.

⁸ <http://www.worldbank.org/>

⁹ Figures in the original table were provided in Malawi kwacha (MK) and have converted to U.S. dollars at a rate of MK140 = \$1USD.

Table 5.1. Total SWAp Allocations

Total SWAp Funding Allocations (billion \$US)					
	GOM	Pool Funders	Discrete Funders	Total	POW
2004/2005	\$ 0.041	\$ 0.008	\$ 0.010	\$ 0.058	\$ 0.074
2005/2006	\$ 0.062	\$ 0.048	\$ 0.002	\$ 0.115	\$ 0.112
2006/2007	\$ 0.055	\$ 0.064	\$ 0.004	\$ 0.123	\$ 0.117

Cumulative Funding Excess (Unspent) (billion \$US)			
	GOM	Donors	Total
2004/2005	\$ 0.014	\$ (0.011)	\$ 0.003
2005/2006	\$ 0.029	\$ 0.001	\$ 0.030
2006/2007	\$ 0.031	\$ 0.009	\$ 0.040

Source: SWAp Mid-Term Review (2007)

EXCESS FUNDING

The slow pace of spending pooled and POW allocations is a major concern, given the health sector needs in Malawi for HIV/AIDS and other EHP services. Although the increased allocated budgets by all partners reflect this need, the excess funding indicates a potential absorptive capacity challenge in GOM health programming.

- In the 2004–2005 period only \$3 million (5 percent) of total SWAp allocations remained unspent, whereas in the 2006–2007 period \$40 million (33 percent) of total allocations were unspent.
- Analysis in the “SWAp Mid-Term Review” indicated that approximately \$11 million remained unspent for medicine procurement in the latest period, with approximately the same unspent for capital expenditures for improving health facilities. Funds in the SWAp account can be carried over to the following year, yet it is undetermined whether that is the case for other bilateral and non-SWAp GOM funds.

5.2 FINDINGS AND OBSERVATIONS

5.2.1 ARV FINANCING

Financing for ART commodities and, to an extent, programming is principally funded by GFATM, which is an official partner in the SWAp and pooled funding mechanism. The funding flows are channeled through the NAC/MOH, which is the principal recipient (PR) of current GFATM support current funding coming from Round 1, Phase II, which is set to end in September 2008. There had been some initial discussion about a no-cost extension of Phase II through March 2009. However, it appears that the consensus is not to pursue this, as those funds may be expended during the original grant period.

In lieu of that extension, Malawi, through its Country Coordinating Mechanism (CCM), has made an application for a six-year grant called a Rolling Continuation Channel (RCC). The RCC option is

awarded to grantees who have demonstrated superior performance in grant managements and results. In effect, it is a continuation and refinement of the main program objectives set out in Round 1, Phase II. Malawi's RCC proposal to GFATM is for a six-year period beginning October 2008. The proposed total budget is approximately \$365 million. The proposed amount for medicine and non-drug health consumable spending is \$157 million. \$23 million is earmarked for procurement and supply chain management strengthening.

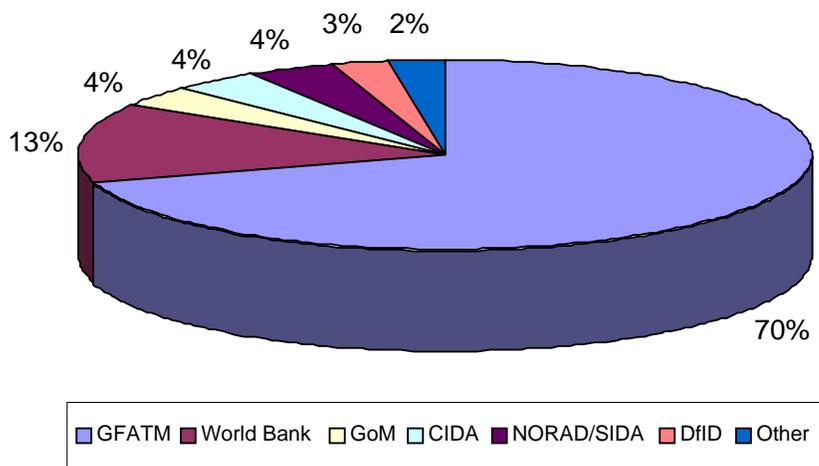
The RCC proposal states that 44 percent of the proposed budget will go to provision of ART (CCM, NAC, and MMOH 2007). However, it is unclear what specific figure is earmarked for ARV procurement. It may be that the HIV/AIDS Unit has not yet quantified or, rather, estimated the total amount needed for ARVs over the six-year period. Nonetheless, the HIV/AIDS Unit would need to continue to quantify specific procurement quantities on a semi-annual basis, as it has done in the current grant period. An indication of potential annual costs for ARVs is provided in the MOH's Five Year Scale-Up Plan 2006–2010. Estimated three-year costs (July 2006–June 2009) for standard first-line therapy was budgeted at nearly \$50 million, with an additional \$7 million procurement budget for alternate first-line and second-line therapy (MMOH 2005).

5.2.1.1 The HIV Pooled Funding Approach

In addition to the broader Health Sector SWAp, there is a parallel funding mechanism for HIV/AIDS programming. The HIV Pool was created in 2004 as a separate but related response to the Health Sector SWAp. There is an MOU between the partners of the two health pools that defines roles and prevents, as much as possible, overlap.

HIV pool basket funders are the GOM, the GFATM, the World Bank, the DfID, the Canadian International Development Agency (CIDA) and the Scandinavian development partners. In 2006 GFATM joined the mechanism. The pool partners operate under joint planning, financing, procurement, and programming across the HIV/AIDS sector. In 2006 GFATM was the largest contributor (70 percent), followed by the World Bank (13 percent). The GOM provided 3.8 percent of the pooled funds through its own revenue during this period. The GOM also made a \$2 million annual contribution toward the cost of NAC operations during this period. It is unclear whether this figure is included in its percentage allocation to the HIV pool.

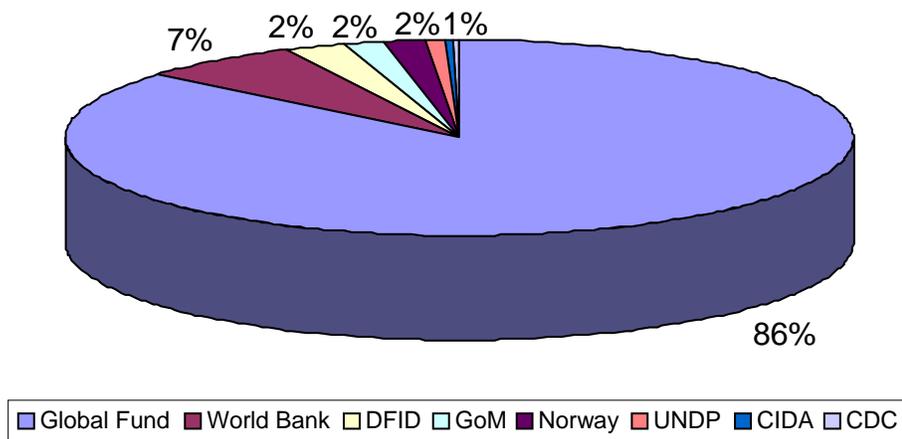
Figure 5.1. Proportion of Funding for HIV/AIDS SWAp Pool 2006–2007



The fiscal year 2007–2008 NAC budget provides an updated view of the proportion of financial support by HIV pool partners. The majority of HIV pool funds flow through NAC, though funds for many vendor payments for procurement and some services are transferred directly from GFATM and other partners to service providers.

Figure 5.2 represents how the proportions have changed in one year. Global Fund contributions to the NAC budget in this period account for 86 percent of the total budget, followed by the World Bank (7 percent), DfID (2 percent), and other sources from 1 to 2 percent. The total budget for this period is \$121.4 million, of which 54 percent was for treatment programs and 13 percent supported prevention. Actual funding received by NAC, compared to budgeted (committed), was 44 percent of the total (\$53 million) (NAC 2008). The consultants were not able to determine the reasons for the margin between committed and received funds for this period or the proportion expended on ARV procurement within the treatment category.

Figure 5.2. FY 2007–2008 NAC Budget Sources for HIV/AIDS Programming



5.2.1.2 ARV Financing Visibility

The team conducted a brief analysis comparing estimated (budgeted) ARV costs with historical procurement costs accessed through the Global Price Reporting Mechanism (GPRM) database. The analysis concluded that there is poor visibility regarding available accurate figures for historical ARV costs and potentially future estimations. Total procurement costs for standard first-line treatments Stavudine (d4T) + Lamivudine (3TC) + Nevirapine (NVP) (Triomune 30 mg and 40 mg) were \$14,080,306 from 2005–2007. Of this total, \$10,552,631 (75 percent) was for the new standard first-line (Triomune 30 mg), which is consistent with the phase-in of the 30-mg strength in place of the use of the 40-mg. The GPRM data, however, are inconsistent with the estimates made in the MOH’s five-year scale-up plan and projected budget, even when the increased patient numbers are taken into account. The scale-up plan budgets approximately \$26 million for standard first-line ARV procurement for in 2006–2007, which amounts to nearly a 90 percent increase over the 2005–2007 (three-year) reported figures in the GPRM database.

Two conclusions are possible and must be considered as potential action items moving forward into the next phase of ARV funding beginning in October 2008.

1. GPRM reporting by the principal recipient is incomplete, accounting for the large discrepancy.
2. Budget estimates in the MOH Scale-Up Plan 2006–2010 are inaccurate and should be revised based on an additional review of patient and consumption data and the assumptions made regarding program scale-up.

5.2.2 CMS PROGRAM DRUG FINANCING

From October 2007 through February 2008, total CMS international competitive bid (ICB) tender value was \$5.5 million.¹⁰ This figure does not include the value of procurements for national tenders. The team was also unable to obtain data on a full previous 12-month financing throughput for CMS, though estimates made in interviews with CMS staff for 2007 put this figure at approximately \$25 to \$30 million annually (ICB and national tendering). This estimate would need to be confirmed with transactional data when it becomes available. The majority of funding for CMS competitively tendered procurements is from the Health Sector SWAp.

With the exception of all drug commodities for ART, which are principally financed from GFATM and procured through UNICEF, the majority of internally financed donated commodities are channeled through the CMS supply system to eliminate parallel supply systems for drugs and medical supplies distribution. NGO-financed commodities, for example, from the Clinton Foundation and others are distributed through CMS. UNICEF, USAID, pharmaceutical company donations and SWAp-financed essential medicines are, for example, financed from separate sources but distributed through CMS.

5.2.2.1 Commodity Budgets and Payment System

District Health Offices and hospitals are provided an annual budget for drug procurement under the GOM's decentralization policy. In general terms, the budget figure, based on available funding for essential medicines and demographic data, is approved by Parliament, then transferred in monthly allocations from the MOF to the MOH, and finally to the health budget centers (DHOs and hospitals). The payment for CMS-procured drugs within the CMS system is based on the CMS procurement cost plus a 12 percent administrative and transport charge intended to partially cover procurement operations at CMS and subsidize vehicle maintenance, repair, stores maintenance, and other capital expenditures not covered by the Treasury or MOH. There is no cost to the DHOs or hospitals (or lower-level health facilities) for donated health products apart from a 5 percent transport surcharge based on the value of product. DHOs and hospitals make requisitions to the RMS. Once the product is received, an invoice is sent to the purchasing facility (DHO, hospital) and payment is made by check for the invoice amount in addition to any charges described above. If product quantities received are lower than what is stated on the invoice, then the purchasing facility pays the amount corresponding to the value of the actual received goods. This situation was described to the team by DHO officials as happening regularly.

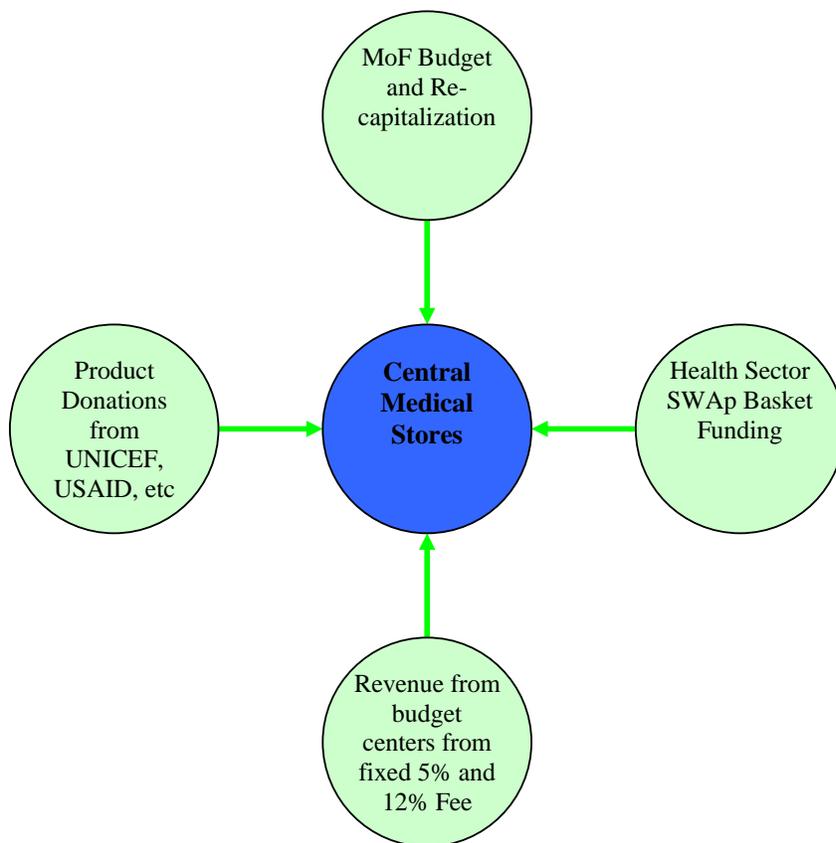
5.2.2.2 CMS Capitalization

There is consensus that the GOM budget for health services and vital essential drugs is insufficient to meet demand, even when including donated products from UNICEF, USAID, and other partners. Further, the MOF provides additional funding to recapitalize the CMS procurement

¹⁰ Data provided by CMS staff, May 2008.

budget to help ensure they have sufficient funds to carry out purchases, in part, because of delays and inefficiencies in obtaining payments from health service budget centers and DHOs. The CMS is in the position of having to pay in advance when buying drug and supplies while having to wait, often for many months, for payment. A study in February 2004 showed that in the first five years of operating as a trust, CMS would need between \$14 million and \$31 million to conduct procurements and pay for operating costs (Glocoms 2007). This consultant team estimates that figure is inadequate, given the increased volume of demand for essential medicines and the plans underway to implement information technology (IT) and organizational reforms. A more recent figure of \$60 million in capitalization for the next two-year period was provided to the team in interviews with key informants. The absence of adequate capitalization has resulted in delays in procurement, reduced quantities in tenders, low stocks at RMS, and stockouts throughout the system (see Table 6.3).

Figure 5.3. Revenue and Product Sources for Central Medical Stores



5.3 RECOMMENDATIONS

ARV Supply System

1. **Conduct a short-term (two-year) quantification of ARV demand for October 2008 through September 2010.**

➤ **Rationale**

The likely transition from UNICEF as a procurement agent to an alternate third party procurement agent for ART products will result in the need for additional coordination, communications and planning between the HIV/AIDS Unit and the third party procurement agent. Further, GFATM and NAC/MOH will require these figures to refine the RCC and plan disbursements, and the volume associated with the quantification will have implications on storage decisions at the central level and in the (already) limited storage space in health facilities.

2. **Conduct a long-term forecast (six-year) of projected ARV demand to determine estimated budget during the GFATM RCC grant period.**

- **Rationale**

A long-term forecast consistent with the RCC grant period is required for the same reasons stated above. The estimated quantities for years 3 through 6 will particularly help inform decisions about central and regional storage requirements and appropriate delivery intervals to ART sites. It will also provide stakeholders, especially GFATM, NAC, and the HIV/AIDS Unit, with the kind of budget visibility needed to make a range of planning decisions.

3. **Ensure that ART product procurement is routinely captured in the GPRM database.**

- **Rationale**

It is necessary to determine actual procurement expenditure and compare it to forecasted expenditures to determine the accuracy of ARV demand projections. At present, in our view, it does not appear that all of the ART procurements (thus, expenditures) for Malawi have been captured in the GPRM database. Alternatively, the forecasted values in the MOH Scale-Up Plan are inaccurate.

CMS Essential Medicine Supply System

1. **Re-examine the 12 percent and 5 percent fee structure in view of actual costs procurement and distribution costs.**

- **Rationale**

A number of DHO and hospital staff interviewed for this assessment indicated that they would like to know the basis from which the 12 percent fee is derived. Many felt the fee was too high and did not reflect actual costs to the CMS for procurement, storage and distribution. An internal cost estimate done for this service would provide the CMS an opportunity to defend current fees or, as the case may be, reduce or increase them.

The specific concern with regard to the 12 percent fee is the additional costs that would be incurred by DHOs and hospitals if and when ARVs are integrated into the CMS distribution system. Costs of first-line ARVs were estimated by the MOH at nearly \$50 million for the four-

year period 2006 through 2009. This amounts to approximately \$6 million in fees that could potentially be incurred by budget centers for first-line therapy alone. Further, this figure would certainly increase as scale-up continues. The team believes a fee-based structure is acceptable but it must be based on costs, and there may need to be exceptions for high-value products such as ARVs. Another alternative would be to budget the CMS distribution and management fee into the funds required of the donor or the SWAp and pay the CMS directly to continue to provide ARVs to the ART centers free of charge.

2. Temporarily increase the amount DHOs and hospitals can spend on private sector commodity purchases from 30 percent of their total drug budget to 60 percent until the stock status of essential medicines and consumables for EHP services at RMS rise above minimal holding levels.

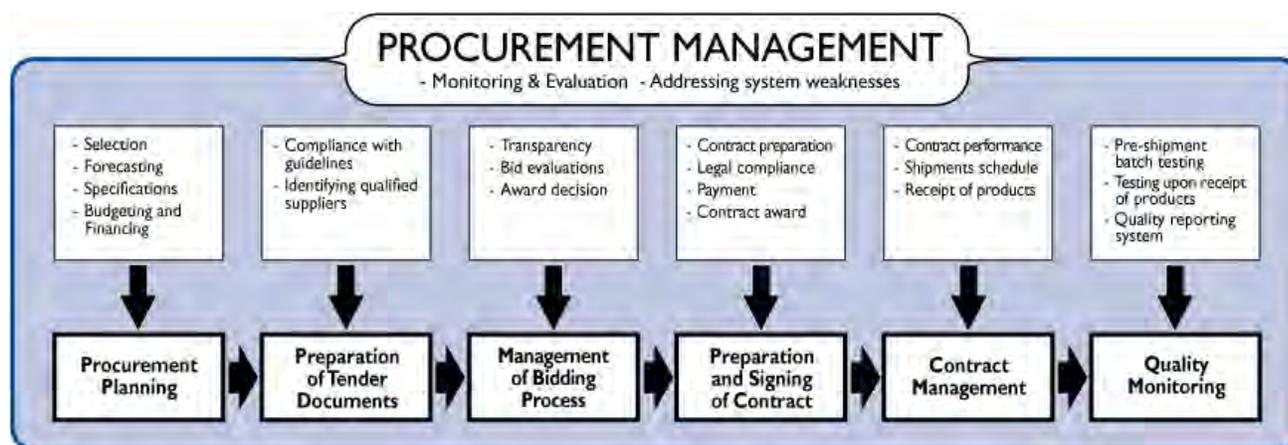
- **Rationale**

An examination of stock cards and information provided in interviews indicate that product availability at RMS is non-existent or well below minimal stock levels for a number of essential medicines, resulting in low or partial order fills for DHOs and hospitals. A temporary increase in the percentage of drug budget these centers are allowed to use will enable them to identify alternative, private sector sources while CMS works to improve stock status. Interviews with DHO staff, somewhat corroborated with the SWAp funding data in Table 6.1, indicate they are unable to spend their drug budgets because of the current 30 percent cap on private sector purchases. If, for example, CMS can only provide 50 percent of stock in a given year, then 20 percent of the DHO budgets would be returned to the Treasury unspent. This should not be allowed to happen while there are stockouts of numerous essential medicines.

6.0 PROCUREMENT

The principles and practice of an effective public sector health commodity procurement system means buying agencies must execute functions in a coordinated way, and share and receive information from downstream clients (health programs and managers) and upstream partners (suppliers, funders, and oversight boards).

Figure 6.1. The Procurement Process



Source: Rao 2006.

The procurement process begins with *selection, forecasting, and quantification* of product requirements. It includes the development of exacting product specifications, identification of financing, and a budget process to secure that financing. As Figure 6.1 illustrates, the process must then successfully orchestrate a number of additional functions, including the preparation of tender documents; management of the bidding process; preparation, award, and management of the contract; quality assurance processes to ensure that only products that meet requirements are accepted for delivery of the contract; and the management and monitoring each of these processes, including supplier performance and product quantification data accuracy (Rao et al. 2006).

6.1 FINDINGS AND OBSERVATIONS

6.1.1 ARV PROCUREMENT

On behalf of the National AIDS Committee (NAC) and the MOH — the principal recipients of GFATM-funded ART procurement — UNICEF procures ARVs and associated ART products (e.g., CPT, HIV rapid test kits, CD4 machines, and reagents). It also donates products through its essential drug program, which are delivered to the CMS for delivery through their integrated essential drug system.

UNICEF generally provides a quality, timely procurement service both for Malawi and many other countries. UNICEF was appointed as the procurement agent in late 2003 because of the absence of PSM capacity in CMS at the time. That decision was intended to be temporary in lieu of adequate

CMS capacity or the appointment of a third party private sector procurement agent. UNICEF does not directly manage every aspect of the ART supply chain. They procure, based on order quantities provided by the HIV/AIDS Unit, and distribute, by private transport supplier (SDV International Logistics) to health facilities.

Table 6.1. Estimated UNICEF Procurement Quantities: 2006–2009

ARV Item	Unit Cost USDS - includes CIF	Numbers of Items / or patients on treatment and estimated cost per 6 month period – includes CIF up to the port of entry						Total number of items	Total cost (USDS)
		Jul-Dec 06 (Order in March 06)	Jan-Jun 07 (Order in Oct 06)	Jul – Dec 07 (Order in March 07)	Jan-Jun 08 (Order in Oct 07)	Jul-Dec 08 (Order in March 08)	Jan – Jun 09 (Order in Oct 08)		
Starter Packs	550	240 \$132,000	270 \$150,000	270 \$150,000	300 \$165,000	300 \$165,000	300 \$165,000	1,680 Starter packs	\$924,000
Continuation Packs	3000	1560 \$4,680,000	2000 \$6,000,000	2600 \$7,800,000	2850 \$8,550,000	3500 \$10,500,000	3830 \$11,490,000	16,340 Cont. packs	\$49,020,000
Alt 1 st Line PN	22 / month	1800 x6 \$240,000	2400 x6 \$315,000	3000 x6 \$400,000	3600 x6 \$475,000	4200 x6 \$550,000	4800 x6 \$634,000	1,190,000 courses	\$2,614,000
Alt 1 st Line HP/SK	42 / month	450 x6 \$113,000	600 x6 \$150,000	750 x6 \$190,000	900 x6 \$226,800	1200 x6 \$302,400	1500 x6 \$378,000	325,000 courses	\$1,360,000
2 nd Line Treatment	95 / month	450 x6 \$256,000	600 x6 \$342,000	800 x6 \$456,000	950 x6 \$542,000	1200 x6 \$684,000	1500 x6 \$855,000	33,000 courses	\$3,135,000
Post-exp Prophylaxis	15 / month		1000 \$15,000		1000 \$15,000			2,00 courses	\$30,000

Source: HIV/AIDS Scale-Up Plan, 2006–2010

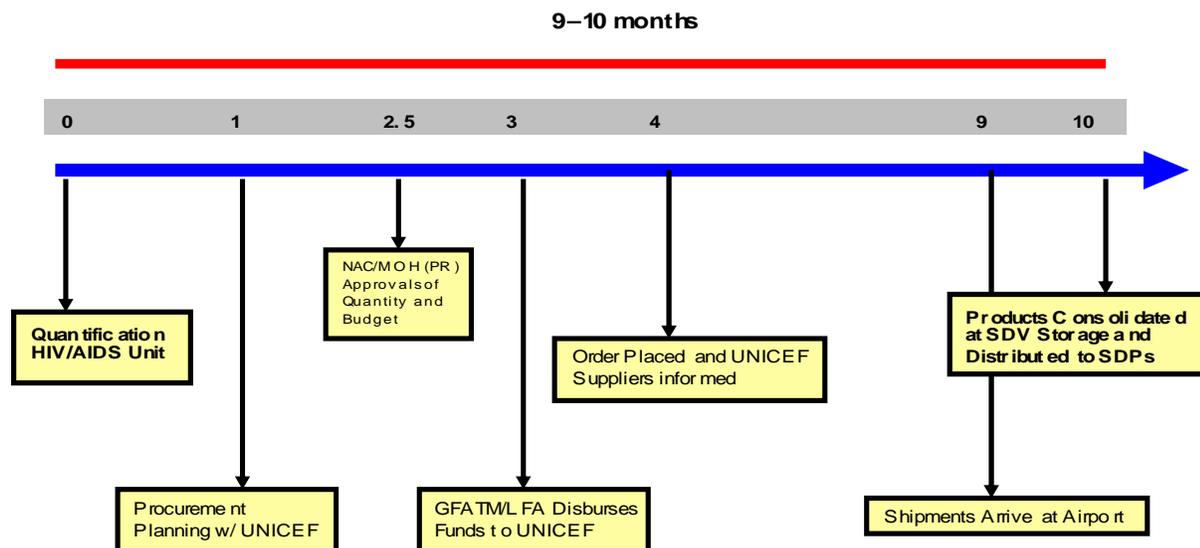
UNICEF procures all of the first-line, alternate first-line, and most of the second-line ARVs for Malawi’s 160 public, NGO, and private ART sites. Procurement quantities for each of these therapies were projected to and have increased substantially in step with the rapid scale-up of ART in Malawi since 2005. As Table 6.1 indicates, estimated three-year costs (July 2006–June 2009) for just standard first-line therapy was budgeted at nearly \$50 million, with an additional \$7 million procurement budget for alternate first-line and second-line therapy.¹¹ UNICEF’s fee for procurement services of medicines ranges from 3 to 8 percent. The ARV fee is 4 percent to cover administrative costs.

6.1.1.1 Lead Time and the Procurement Process Steps

A guiding management principle imbedded in the procurement process is to minimize the holding time for ARVs trans-shipped to ART sites. The maximum desired trans-shipment time at SDV’s leased warehouse near Lilongwe’s airport is two weeks after arrival. In practice, the holding time is often longer (four weeks) because SDV (to manage distribution and product use more effectively) is forced to wait on multiple shipments to arrive from different manufacturers (e.g., CPT, which comes from one manufacturer, and Triomune arriving from Cipla in India) and then repackage items for facility distribution. The situation has had minimal impact on product availability, as the longer holding period does not occur on a routine basis and several emergency orders have been placed to address stock shortages. Nonetheless, ARV receipts planning is an issue that needs to be addressed to reduce lead times.

¹¹ The team was able to obtain only estimated (not actual) budget figures.

Figure 6.2. Average Lead Time and Procurement Steps for ARVs



The procurement process steps and average lead times are illustrated in Figure 6.2. Average lead times from quantification and order planning to product arrival in health centers is 9 to 10 months. This process can be reduced through faster signature approvals from NAC for the budget and order quantities; through more efficient response time between order placement and shipment arrivals (currently five months); and improved order planning, which would reduce the consignment consolidation period at SDV’s trans-shipment warehouse near Kamazu International Airport. Despite these potential improvements, UNICEF procurement performance has generally been timely, resulting in the avoidance of large-scale low-stock situations at ART sites. Unit prices have been competitive with median reference prices, and problems related to product quality and limited shelf-life consignments have not been reported. In short, the system is working. However, the arrangement, as previously described, was designed to be temporary for a number of reasons listed in Recommendation 2 in Section 6.2 (below).

6.1.2 CMS PROCUREMENT

6.1.2.1 Institutional Arrangement

The CMS is a Treasury-funded institution supervised by the MOH. It is charged with the procurement of medicines and non-drug consumables (NDCs) for all GOM service delivery points (SDPs) (through DHOs), public hospitals, Christian Health Association of Malawi (CHAM) and other NGO and private sector facilities. The Director reports to the Deputy Director for Pharmaceuticals, Directorate of Health Technical Services (DHTSS). The CMS has a separate account from the MOH for operations. The Medical Buying Committee (MDC) is charged with reviewing and approving all procurement contracts proposed by a technical review committee. Health basket-funded products must also be approved by the SWAp donor partner coordinating procurement, the World Bank. The CMS works closely with the Pharmacy, Medicines and Poisons Board on registration of drugs and sample testing of consignments received in its receipt section of the warehouse in Lilongwe it shares with the Central Region RMS. The CMS has three regional branches (RMSs), in Blantyre, Lilongwe and Mzuzu (Glocoms 2007).

6.1.2.2 Mission

CMS is responsible for procuring all products in its catalogue, which has been developed in accordance with the essential medicines list. CMS prepares an annual procurement plan that is approved by the MOH. In concept, the CMS procures products with its own revenue collected from sales to DHOs, hospitals, and NGOs. In practice, the CMS does not have the financial resources to do this. Instead, it receives capitalization for drug procurement from the MOH (mostly through SWAp funding) and also provides a drug budget for DHOs. The procurement plan is based on estimates of yearly consumption, the stock situation, and the drug budget, among other factors. In practice, limited consumption data are available, which forces the CMS to rely on demographic estimates and an allocation system by region. Due to limited funding, the primary focus should be on the procurement of vital products on the Malawi Essential Medicines List (MEML). In practice, procurement and allocation decisions are based on estimates of customer demand derived from RMS issues data (as available). Following approval of the procurement plan — now done in two-year framework contracts — CMS prepares tender documents which are then issued (open tender) to initiate the process of acquiring products from international and national suppliers and manufacturers. In accordance with the provisions in the Procurement Act No. 8 of 2003, tender evaluation and awarding of any drug supply contract whose value is above MK800,000 is done by the Medical Buying Committee (MBC), composed of the Permanent Health Secretary, Ministry directors (including the director of HTSS, PMPB, and a senior staff member from the Office of Director of Public Procurement (ODPP) (O&M 2007).

CMS currently has no central warehouse space. The unit is intended to conduct procurement and pass products directly to the Regional Medical Stores. The Central RMS is located in Lilongwe in the same building as the CMS; the Southern RMS is in Blantyre and another is in the North. Product consignments reaching CMS go to a small “receipts section” of the building where samples are taken and tested by the PMPB. Upon passing safety tests, the products are released to the RMSs. If no space is available in the receipts section, then they are released directly to the intended RMS warehouse and a sample is sent back to the laboratory for testing.

6.1.2.3 The Cost of Poor Supplier Visibility

Essential drugs procured by the CMS arrive at the airport in Lilongwe and, by road, through border crossings with Mozambique. At each port of entry, consignment forms and products are reviewed by customs officials and are then allowed to proceed either directly to CMS for intake into the system or to an RMS if the CMS receipts section is full. The process also includes matching consignment numbers to the invoice and random batch sample testing of the product in the laboratory located within the CMS.

Because the procurement delivery schedules are not staggered to allow for scheduled receipts that correspond to available space in the receipts section in CMS, consignments are put into demurrage storage at the CMS freight forwarder, Allied Shipping, at their warehouse in Kanego (Lilongwe district), which is approximately 10 km from CMS, near the KIA International Airport. The Allied storage facility acts as a de facto central storage facility because of a lack of storage space at the CMS receipts facility and ineffective shipment scheduling. The CMS staff interviewed by the team indicated that they would like to re-evaluate order flows to correspond to storage space. However, their view, which is for the most part accurate, is that they do not have visibility into demand and so cannot plan product arrivals to correspond to RMS projected issues. Therefore, a *receipts planning strategy* is not in effect at CMS because they contend they have no visibility into demand. In the short term, inventory counts and review of issues data from the RMSs could help alleviate the bottleneck, but

RMSs currently have no way to obtain total facility inventory without a manual stock count and/or review of each stock card in their warehouses — a process that shuts down distribution for two weeks. In effect, the lack of routine data and the subsequent inefficient order planning negates many of the benefits of the two-year framework contracts under which the recent receipts have been arriving.

CMS has not automated supplier performance and upstream pipeline monitoring. They use an Excel spreadsheet to enter data when orders have been placed, but do not routinely monitor arrival dates against order placement dates to determine supplier performance. The data exist in the form of paper invoices but are not combined with order information to produce any visibility on supplier performance.

Payment Efficiency

Interviews with CMS staff indicated that vendor payment efficiency remains a gap because incoming procurement quantities are not planned in a way to stagger arrivals. As a result, incoming consignments destined for the receipts section in CMS become bottlenecked in a waiting line of trucks preparing for inspection and testing, or they are put into demurrage at Allied's facility (donated products are not sample tested). Because of this, final payment cannot be issued to vendors until products are received and tested. The additional time means that the payment terms of the vendor contract are often violated, resulting in penalties for late payment.

6.1.2.4 Consumption Data for Procurement Decision Making

In an effort to build capacity within the CMS, the MOH and other Health Sector SWAp partners agreed to move forward with a CMS procurement of Depo-Provera. (In the past, the product had been supplied directly from UNFPA, and is still provided through USAID.) In December 2007 the first half of the order (900,000 vials) arrived at the CMS at a unit of price of \$0.90/vial.¹² CMS successfully managed this tender and, in fact, was able to procure it well below the median procurement price of \$1.10/vial.¹³ The second half of the order is expected to arrive sometime in the spring of 2008.

CMS followed the established procurement process in its SOPs in preparing the tender documents, reviewing and awarding the bid. Despite this, the order quantities were not informed by existing consumption data from health centers or product issue data from the RMSs.

Four and one-half million units of Depo-Provera were forecasted for the two-year period (2008–2009).

Some stakeholders interviewed suggested that number may have been slightly high, indicating that only 4 million units were needed. Nonetheless, the CMS procured only 1.8 million units, arguing that, despite the presence of consumption based forecasts, the DHO health offices would only requisition the lower amount. Though it is too early to determine with certainty, stock-level counts at RMSs and reports from facilities indicate that the 1.8 million unit procurement was insufficient. A review of the stock cards at RMS Central at the time of visit indicated less than one month's supply of Depo-Provera.

Second, the consumption data were not used to allocate the product based on demand by region. Instead, the CMS allocated the product using the demographic formula used for most essential medicine distribution to the regions: 45 percent (South), 35 percent (Central), and 20 percent

¹² Data obtained from CMS staff.

¹³ Management Sciences for Health. *the International Drug Price Indicator Guide, 2007*

Comparing Lead Times: ARVs and Essential Medicines

The segment accounting for the longer lead times for CMS-procured products is the period between contract signature and product arrival. By contrast, order placement and shipment arrival are, on average, five months. Each of these segments account for the longest lead in both supply chains — as they do in most programs. However, average lead times for ARVs are approximately one-half of those of CMS. This fact should raise concern regarding the current capacity of CMS to effectively integrate ARV procurement in the near term.

Average lead times from quantification to arrival of first consignment are approximately 18 months, sometimes longer (Figure 6.3). The greatest proportion of the interval occurs between supplier contract signature and arrival of the shipment (average 10 months). Generally, a period of 8 to 12 months is established in the contract, providing suppliers a sufficient timeframe to deliver products. However, the lead times

from quantification to arrival of first consignments are longer due to supplier selection, Medical Buying Committee (MBC) recommendations, and ODPP and World Bank “no objection” letters regarding the proposed bidder.

The lead times should decrease because of the introduction at CMS of the two-year framework contracts, which do not require an annual rebidding process. Therefore, the process should, in effect, be reduced to two functions following the arrival of the initial consignment in the framework contract: (1) review of product demand; and (2) and reordering supplies from the vendor through the period established in the framework contract.

6.1.2.6 CMS Product Availability

A central requirement of integrating ARV procurement and distribution into the CMS essential drug system is routine availability of products at the RMS warehouses for distribution to ART health facilities. Since 2004, the MOH HIV/AIDS Unit has been able to successfully monitor stock status and patient numbers on a quarterly basis and use that data to make accurate forecasts of annual ARV demand. The Unit then works with UNICEF procurement specialists to ensure products are purchased and distributed to health centers with very few incidents of stockouts. The CMS has been more challenged to provide this same level of service to health centers for essential medicines availability and continues to face stockouts and low supply. Though the range of products procured by CMS is much broader than those procured by UNICEF for the ART program, this issue must be addressed before procurement and distribution can be successfully integrated into the CMS system.

Table 6.2 represents the service performance of one RMS to a major urban hospital in 2006 and 2007.¹⁴ In 2006, an average of 34 percent of 146 essential medicines and consumables (median figure) requisitioned by the facility were out of stock (O/S), while only 33 percent were in full supply (F/S). An average of 49 percent of 160 essential products was O/S in 2007, and only 22 percent were in full supply. The data from the urban hospital show that stockouts at the RMS have increased by an average of 15 percent from 2006 to 2007. It is cautioned that the figures represent data from only one facility’s requisition history for one of three RMSs. However, anecdotal evidence and interviews with staff at other health centers suggest that supply availability figures at other RMS for other facilities are consistent with these figures.

¹⁴ No data were available for May and June, 2006.

Table 6.2. Percentage Product Availability at RMS from Facility Requisition, 2006 and 2007

Month	Jan-06	Feb-06	Mar-06	Apr-06	May-06	Jun-06	Jul-06	Aug-06	Sep-06	Oct-06	Nov-06	Dec-06	Average
F/S	18%	40%	26%	31%			39%	35%	34%	27%	54%	26%	33%
S/S	55%	34%	35%	44%			28%	32%	21%	25%	25%	35%	33%
O/S	28%	25%	39%	25%			33%	33%	44%	49%	21%	40%	34%

Month	Jan-07	Feb-07	Mar-07	Apr-07	May-07	Jun-07	Jul-07	Aug-07	Sep-07	Oct-07	Nov-07	Dec-07	Average
F/S	30%	35%	13%	14%	28%	17%	12%	22%	18%	8%	20%	23%	22%
S/S	49%	43%	41%	37%	31%	43%	35%	25%	33%	40%	26%	26%	39%
O/S	21%	22%	47%	49%	41%	40%	53%	53%	49%	52%	54%	50%	49%

Source: Hospital pharmacy records, May 2008.

F/S: Full Supply

S/S: Some Stock

O/S: Out of Stock

Private Wholesale Procurement

Consequently, DHOs and hospitals have been forced to rely upon their drug budgets to conduct local procurements from the private sector in the absence of stock at CMS. This is one of the biggest challenges faced by the DHOs and hospitals. CMS often either provides limited stock or is stocked out of products they requisition. A DHO can spend up to 30 percent of its drug budget on private wholesale procurement for essential drugs. However, a large portion of its drug budget remains unspent because of this limitation. If DHOs can spend only 30 percent of their drug budgets on wholesale procurement, and, based on their experience over the past years, the CMS can only supply 40 percent of the volume of their requisitions (this is consistent with the data in Table 6.2), then up to 30 percent of their annual drug budgets goes unspent and must be returned to the Treasury.

Kamuzu Central Hospital estimates that they buy 40 percent of their essential medicine stock through private wholesale procurement.

However, DHO and hospital private sector procurement does consume additional staff time and requires a commitment to a process that can take more than three weeks to:

- Get authorization from CMS (two days).
- Solicit bids/pro forma invoices from three vendors (one if sole source) (seven days).
- Allow the procurement committee at DHO to review bids and select vendor (two days).
- Allow the accountant to prepare and issue a check (10 days).
- Have product ready for delivery following receipt of check by vendor (three days; they have to use their own vehicles).

6.2 RECOMMENDATIONS

1. Maintain ARV procurement vertical to the CMS logistics system.

- **Rationale**

The absence of supplier visibility, limited use of consumption data for procurement decisions, and lengthy lead times have resulted in inadequate product availability for DHOs, hospitals, and lower-tier health centers. The organizational challenges associated with CMS as an institution — chiefly, the inability to maintain a sufficient cadre of skilled procurement professionals — is a primary factor limiting the CMS to these inadequate performance measures. The institution must first take measures to address these gaps, as described in the following recommendations and in each section of this report, before consideration should be given to full-scale integration of ARVs and associated ART products.

2. Select a private sector third party agent to (1) conduct ART procurement, and (2) work in concert with CMS, not apart from it, to build the requisite procurement management and technical capacity for a range of ART products and essential medicines.

- **Rationale**

Third Party Procurement Agent

First, a third party agent is required to successfully deliver procurement services for the ART program due to the capacity constraints documented in the preceding section. UNICEF was appointed as the procurement agent because a GFATM-supported PSM capacity assessment concluded it was the optimal course of action to implement Round II grant procurement. This decision was intended to be a temporary action in lieu of adequate CMS procurement capacity or the appointment of a third party private sector procurement agent. The temporary nature of the appointment stems from an agreement between GFATM, UNICEF, and the MOH that UNICEF would provide procurement and distribution services in an interim capacity. Secondly, UNICEF's position, as a policy, is that it does not wish to carry out functions which the government could do if adequately capacitated. This is the primary reason why UNICEF is keen on capacity-building alongside providing procurement services to countries in need of their services. In addition, on a legal basis, the absence of certain UNICEF procedural clauses means that UNICEF is “technically” noncompliant with World Bank bidding procedures. Because GFATM and the MOH are members of the SWAp health basket funding mechanism, any third party agent selected would need to adhere to the regulations and clauses set out in World Bank standard bidding documents and regulations governing procurement of health commodities. Many partners view UNICEF's continued role as a procurement agent for GFATM/NAC-financed ARVs and associated ART products to be in conflict with the SWAp partnership agreement. However, this point is debatable. Many involved contend that the funding for ART supplies is not from World Bank or SWAp, and therefore World Bank regulations regarding some of these more detailed clauses do not have any regulatory or legal standing.

Second, another area of concern regarding the continued role of UNICEF as a procurement agent is the dual role it plays as both a vendor/service provider to NAC/MOH for ARV procurement and as a development agency. This sometimes results in less than responsive customer service to NAC than would be provided by a truly commercial entity offering the same services. For example, one of the key disbursement requirements imposed on PRs is for them to enter previous procurement data (e.g., unit cost, volume, dates, supplier) in the Global Price Reporting Mechanism (GPRM) before any funds can be disbursed for the following

procurement. Although UNICEF has improved efforts in this area, the team was told that they have sometimes been slow to respond to NAC requests for the procurement data, which it must enter into the Web-based system. The result is a delay in disbursement of funds and the overall procurement process, which increases the lead time between when ARVs are quantified and when they arrive.

Third, and no doubt the most controversial, is a concern regarding contracting terms in UNICEF's standard agreements. It requires that all funds for medicine procurements be in its account before it will initiate the procurement process. There is understandably an element of risk coverage in this policy. However, most commercial supplier contracts with customers require an initial percentage paid at contract signing, then the remainder upon receipt in-country and quality testing. This arrangement motivates both vendor and customer to perform in a manner consistent with the contract terms. Although UNICEF's performance has been consistent and successful in procuring and distributing ARVs, its payment terms are not consistent with most commercial practices. NAC/GFATM is required to provide UNICEF the entire estimated amount for each procurement before UNICEF initiates the procurement process. Further, the team was told that the contracts allow for up to 12 months after receipt of funds to deliver ARVs. With procurement costs ranging from \$5 million to than \$10 million per order, there is a substantial cost of capital for the customer in ensuring full procurement costs are advanced 7 to 10 months before the products arrive. It is, however, necessary to point out that UNICEF has not billed itself as a commercial procurement agent. It does not have the financial resources to accrue significant expenditures for covering risks such as payment defaults, late payments, etc. UNICEF cannot therefore be expected to provide procurement service on the same terms as a commercial procurement agent.

Linking Services

The consultant team discussed and concluded that third party procurement services for ARVs (and other ART products currently procured by UNICEF) and procurement capacity-building are two distinct services. Linking these services under a single contract would have the consequence of (1) limiting the number of qualified providers able to provide both services; (2) increasing the complexity of a potential terms of reference (TOR) for the combined services tender; and (3) extending UNICEF's mandate beyond the end of GFATM's Round 2, Phase II grant, set to expire at the end of September 2008.

With those concerns in mind, the approach nevertheless provides distinct advantages:

1. It links procurement capacity building for ARV (and ART) procurement with the need to improve capacity for essential medicine procurement at CMS. Currently, there is no technical link between CMS and UNICEF, apart from distribution. Procurement capacity is not transferred from UNICEF to CMS for ARVs because procurements are done vertically. Linking these functions will provide the CMS with direct exposure to ART procurement, thereby improving their expertise with these products and increasing the time frame in which to consider a subsequent integration.
2. Bundling these services would decrease the management burden on CMS. Instead of managing two contracts and two bid processes, and working with a third party procurement agent and a separate technical assistance provider(s) for capacity-building, integrating these services in one tender will reduce the burden on an already overstretched management staff.

The arrangement in the services tender would also include a clause allowing CMS to seek additional technical assistance for any function it may choose (e.g., other program-specific expertise such as reproductive health (RH) products, distribution, information management systems), provided there is budget.

3. The coupling of the two services may also facilitate procurement capacity training for CMS staff. A handful of organizations that serve as third party procurement agents (such as IDA and Crown Agents) also have divisions and separately incorporated but linked entities that provide procurement capacity development services. These training/capacity-building services are often consistent with the methodology employed by the sections that carry out the procurements, providing CMS with an integrated package of services.

3. Maintain UNICEF ART procurement and distribution services for products quantified in March 2009 and distributed in October 2009.

- The HIV/AIDS Unit and UNICEF should proceed with the September 2008 quantification and ordering for the anticipated April 2009 shipment (the October 2008 order is already in the pipeline using GFATM Phase II funding).
- The same process should continue for the March 2009 quantification and order, for distribution in October 2009, noting that some of the supplies that would be scheduled for that delivery would arrive after October. Therefore, close attention to the transition would be critically important.
- If NAC, GFATM, and partners begin the TOR development and tender process in July 2008, this recommendation would provide them with a 14-month window in which to select a third party procurement agent and capacity development services.

- **Rationale**

Floating a tender for combined or even disaggregated procurement services (third party agent and capacity building) will no doubt take time and effort. The GOM cannot afford to compromise the level of service it has received from UNICEF during this period. Therefore, it is recommended that an agreement should be reached with UNICEF by NAC/MOH and GFATM to continue to provide procurement services through the first year of the RCC, provided the grant application is formally approved.

4. Phase-in CMS procurement of one ART-related product annually, beginning with HIV rapid test kits (2009) and co-trimoxazole prevention therapy (CPT) 120-capsule units (2010).

- **Rationale**

Despite the capacity gaps described in this report, CMS does maintain a degree of capacity to procure and distribute essential medicines. Lead times are indeed long and there is an absence of data for procurement decisions. However, over the course of the third and fourth quarter of 2008 CMS has taken steps to address some of the human resource concerns, and is beginning to work closely with the USAID | DELIVER Project for capacity building and training on a range of supply chain issues. CMS has, for example, begun to distribute HIV rapid test kits and certain medicines for OIs procured by UNICEF. Further, it has implemented a new two-year

framework contract practice that may start to pay dividends as it works on order planning and pipeline monitoring. Therefore, the consultant team suggests a phased approach for the procurement of two ART-related products, with a third to be decided based on circumstances following performance measurement of procurement management in years 1 and 2 and subject to the implementation of the third party agent who could oversee the PSM process (see Recommendation 2 above).

5. Decrease lead times within the ART- and CMS-managed essential medicines system.

- Improving the management and coordination of procurement data entry into the GPRM between UNICEF and NAC will decrease the time between these steps.
- Improved order planning by UNICEF can shorten the duration of time ART products must be kept in storage by SDV.
- Improved tender documents prepared by CMS, which include but are not limited to detailing product specifications, will shorten time required for “no objection” letters from the World Bank.
- CMS needs to put in place supplier performance monitoring tools, including off-the-shelf software that monitors order placement dates with arrivals to determine how they can decrease this interval.

• Rationale

Long lead times have the direct effect of forcing storage facilities and health centers to hold larger amounts of safety stock. Long lead times also increase storage costs; higher storage volumes mean more space and resources needed to maintain stock levels. Long lead times also require correspondingly longer intervals between product replenishments.

Average procurement lead times for ARVs (Figure 6.2) are up to 10 months. Anecdotal evidence obtained by the consultant team from interviews with UNICEF, the HIV/AIDS Unit, and SDV indicate that may be increasing. The interval required in the period before the disbursement of GFATM funds to UNICEF is a bottleneck, taking from one to two months. Improving the speed with which UNICEF provides procurement data to NAC will decrease the time between these steps. Further, improved order planning by UNICEF can shorten the duration of time ART products must be kept in storage by SDV, as they wait for multiple consignments from different manufacturers before making deliveries. *Further, any third party agent selected to replace UNICEF procurement, will also have to address these same challenges.*

Improved tender documents prepared by CMS, which include but are not limited to detailing product specifications (e.g., strength, dose, presentation), will also reduce the lead time for CMS with regard to obtaining “no objection” letters from the World Bank when they procure with SWAp/health basket funds. Second, CMS needs to put in place supplier performance monitoring tools to, for example, compare order placement dates with arrival dates to measure supplier lead time, to identify the choke points, and determine how they can decrease the overall lead time.

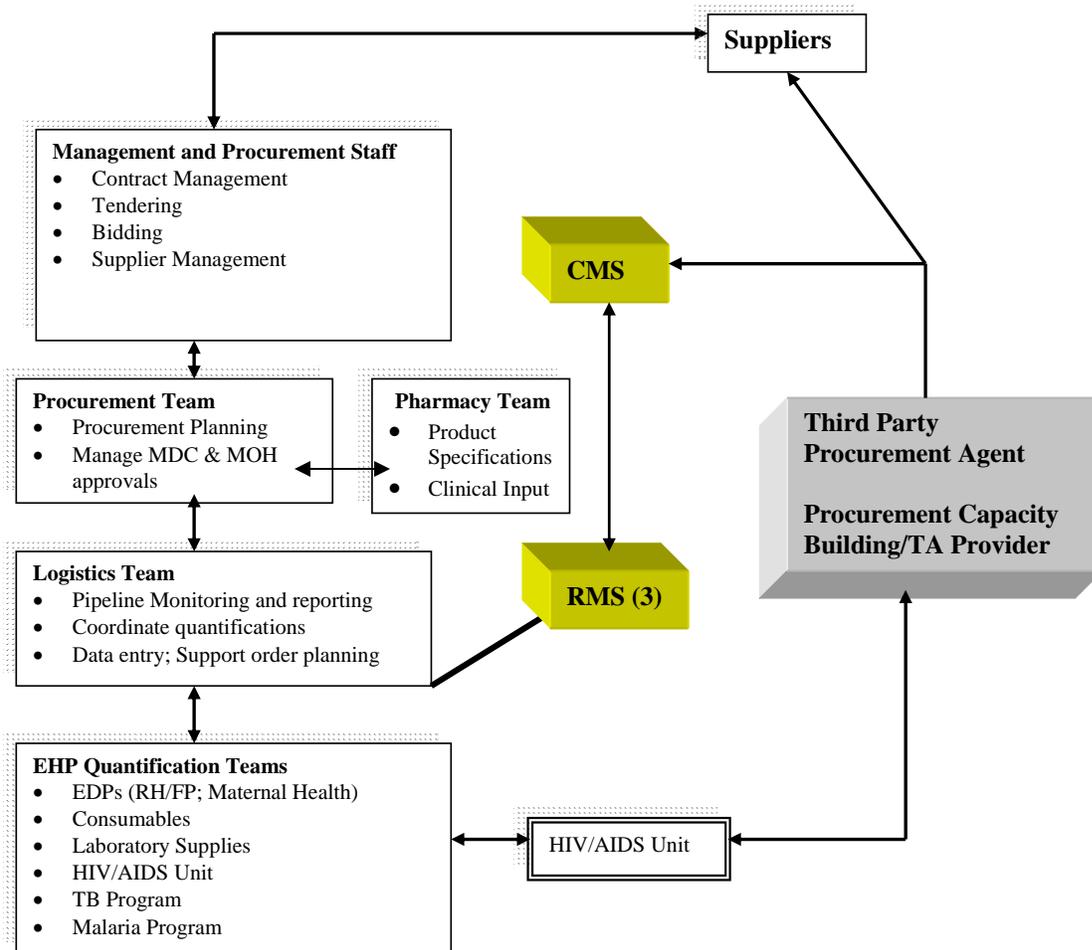
6. Reorganize the internal structure of CMS to:

- **Improve the use of consumption data for procurement decisions.**
- **Provide accurate, routine pipeline monitoring information to programs.**

- Improve supplier visibility and performance for programs.
- Track supplier performance.
- **Rationale**

The USAID | DELIVER Project’s Lilongwe office has proposed that a Procurement and Supply Chain Unit be created within CMS to link product selection, forecasting and quantification with the upstream processes, including supplier visibility, order planning, and pipeline monitoring. Figure 6.4 illustrates the recommended reorganization and reorientation of CMS structures to create the vital link between consumption data moving upstream and pipeline/supplier data moving downstream to inform programs on order quantities and expected delivery dates. The diagram also outlines how the proposed third party procurement agent for ARVs and capacity building function would integrate with the proposed structure.

Figure 6.4. Proposed CMS Organizational and Information Flow Diagram



The primary purpose of the proposed structure is to make CMS more responsive to the supply needs of the programs and install staff at CMS who can provide pipeline monitoring information. Currently, especially since the Glocoms departure, it is very difficult to determine lead times or to know order status. Nor is there necessarily any clear link between forecasted demand for essential medicines and procurement quantities, as demonstrated by the recent Depo-Provera procurement. Management at CMS agreed that the institution must shift the focus away from the use of demographic data and assumptions leading to the current allocation system, to consumption and issues data reported from each RMS. This would in turn provide data for the Quantification Teams — made up of experts from various EHP programs — to conduct annual or semi-annual forecasting exercises with the participation of the proposed logistics team within CMS. The Logistics Team would then be able to provide the Procurement Officer and Pharmacist-in-Charge with more accurate forecast quantity data and product specifications, which would then be reviewed by the pharmacists, working as part of a team with the Procurement Team. This team would in turn inform the Contracts Management and Procurement Team, who would develop tenders and interface with suppliers on a routine basis to obtain order status visibility. Finally, this data would be communicated back down the chain to programs in the form of pipeline monitoring data. The main interface with the programs for this data flowing back downstream would be the Logistics Team.

For ART products, the proposed third party procurement agent would exchange information with both the suppliers and with the CMS team. Further, the HIV/AIDS Unit would interface directly with the proposed third party procurement agent to provide routine order quantities from its semi-annual quantification exercises. It is suggested, nonetheless, that the Unit conduct these exercises in conjunction with the other programs as part of the quantification team, even though ART data management will remain vertical.

7.0 WAREHOUSING AND INVENTORY CONTROL

7.1 FINDINGS AND OBSERVATIONS

From the team's observations, there seems to be no overlap between ARVs and CMS-managed essential medicines in either warehousing or in inventory control. ARVs arrive in Lilongwe and are distributed by a third party logistics contractor from its store directly to the ART centers based on an allocation determined by the HIV/AIDS Unit. Essential medicines are allocated (through the CMS receipts) section to three RMSs. The RMSs, in turn, fill requisitions made by the DHOs on behalf of service delivery points. ARVs are managed by a dedicated, well-paid team whereas essential medicines management depends on government personnel seconded to the CMS from other ministries, often for only a single year's commitment. Different personnel with access to different resources are managing different procedures. Not surprisingly, the performance of these two systems is different, with ARV supply management performing well and essential medicines less so.

7.1.1 ARV SUPPLY MANAGEMENT

The HIV/AIDS Unit, UNICEF and the Clinton Foundation work together to ensure that ARVs are supplied to the 118 public health facilities and 45 private sector/NGO facilities providing ART. The HIV/AIDS Unit is responsible for determining the quantities of ARVs to allocate to the facilities. The bulk of the central-level storage is managed through a third party contract between SDV Malawi Ltd. and UNICEF. SDV Malawi Ltd. performs the same four tasks under its contracts with UNICEF and Clinton Foundation:

- Customs clearance
- Temporary storage
- Break-bulk and packing for distribution
- Physical distribution to the ART centers

Physical space at SDV Malawi Ltd. appeared adequate in the main, 730 square meters of storage area at the time of the visit. This is the space SDV uses to break down the shipments into cartons and reorganize them for distribution to the ART centers. The space was clean and, on brief observation, well organized, with pallets not exceeding the recommended height and sufficient aisle space for personnel to work. We had to pass security at the main gate and were escorted by a security guard through the warehouse to the management office.

SDV manages an additional 447-square meter emergency storage area for UNICEF goods only. There is also an additional 228 square meters available for management by customs.

All ARVs come as air freight; individual shipments range from 500 kg up to 12 metric tons. The typical shipments are between 3 and 5 metric tons and, according to SDV, it processes about 40 shipments of ARVs per year for UNICEF.

In principle, SDV does not hold ARV inventory beyond what is required to manage a single allocation. Distribution lead time can be up to six weeks from receipt of shipment.

By design, inventory levels at the ART centers should be between two and eight months of stock because resupply frequency is semi-annual. However, discussions with SDV Malawi Ltd. and the ART sites indicate that, in practice, resupply may also occur on 4-month, 6-month, or 12-month intervals.

7.1.2 CMS SUPPLY SYSTEM

The CMS system manages the distribution of more than 2,000 different medicines, equipment and non-drug consumables to roughly 366 government public health centers in 27 districts, 30 hospitals, and more than 150 CHAM health centers and other NGO centers. The CMS manages diverse storage locations. The Central RMS, itself is located in Lilongwe in the same building as the CMS. The Southern RMS is in Blantyre and the third RMS is in Mzuzu serving the North.

Product consignments reaching CMS go to a “receipts section,” either in Lilongwe or Blantyre, where samples are taken and tested by the National Drug Regulatory Authority (NDRA). Upon passing safety tests, the products are released to the RMSs. If no space is available in the receipts section, product may either be held in temporary storage at the port, with the CMS’s freight forwarding agent, Allied Shipping, or simply released directly to the intended RMS warehouse. In any case, a sample is sent back to the laboratory for quality control testing. All of these options, while demonstrating CMS flexibility and resourcefulness, underscore the fact that physical storage space is not sufficient for their throughput as currently managed. The receipts section in Lilongwe, for example, has no capacity for lifting pallets (they do have a pallet truck). All receipts have to be broken down for movement by hand. In any case, the section is so full there would be no room to maneuver a forklift.

Although the purpose of this assessment was not a detailed assessment of RMS storage, it needs to be noted that warehouse conditions in the two RMSs visited, Southern Region and Central Region, do not conform to all of the norms for proper storage. While both stores were dry and well-ventilated, they were also overcrowded, making it difficult to manage first expiry/first out (FEFO). The floor in the store in Blantyre was littered and, consistent with the overcrowding, pallets and racks were stacked too high, resulting in crushing damage to the cartons below. In one case, a pallet on a rack had slipped partway off of its rails and its load, already above the recommended pallet height, balanced precariously over an aisle. No one would say how long it had remained so.

According to key informants at the CMS, the available space in the receipts section is often overwhelmed because the procurement receipt schedules are not staggered. Consignments are put into demurrage storage at CMS freight forwarder Allied Shipping at their warehouse in Kanengo (Lilongwe district), approximately 10 km from CMS near the airport. The Allied facility acts as a de facto central storage facility because of a lack of storage space at the CMS receipts facility and ineffective shipment scheduling. The CMS staff interviewed by the team indicated that they would like to re-evaluate order flows to correspond to storage space.

Some plans are already in the works at the RMS for the future storage of ARVs. The Pharmacist-in-Charge in the Southern Region described how they plan to free up 108 square meters of floor space (9 m × 12 m) for ARVs in the main store by removing the unused shelves and the expired goods from the store. The ceiling was low in the proposed area of the store, so racking is not a possibility.

This would allow the RMS roughly 134 cubic meters of storage of ARVs ($108 \text{ m}^2 \times 0.5 \times 2.5 \text{ m}$). The area would need to be isolated with a fence for security purposes if this option is pursued.

Stock location at both RMS sites visited depends on clerks knowledgeable about put-away. There is no recordkeeping regarding location of goods in the stores, which can be particularly problematic considering the large numbers of SKUs.

Security was also an issue at the stores. There were no security personnel present in the warehouse at the time of visit, although we were informed that guards are posted at night and both sites are within fenced compounds.

Health center visits concentrated on the ART centers, so no comment can be made regarding the conditions of the main stores at the hospitals.

Inventory Levels

According to the system design, the RMSs are supposed to maintain inventory levels between six and twelve months of stock. The RMSs manage inventory using stock cards, so it is possible to compare inventory as recorded on the stock card to the inventory policy. At the Central RMS, a review of stock cards for seven tracer products indicated that five of the essential medicines (71 percent) were below a minimum stock level of six months established in the standard operating procedures. Using previous month's issues data, Table 7.1 shows that there was only a little more than one-half month's supply of Depo-Provera and only one day's stock of Ciprofloxacin at the RMS. For an eighth product, Determine HIV rapid test kits, the stock status could not be determined because there was no stock card. Only two of the eight products were stocked according to plan and two products were close to stockout.

Table 7.1. RMS Stock Status of Essential Medicines (Tracer List at the Central RMS)

Product	Strength	Total Stock (in units)	Months of Stock
Sulfadox/P	500/25 mg	715,000	1.5
Depo-Provera	150 mg	54,692	.6
Co-trimoxazole	480 mg	1,618,000	1.3
Erythromycin	250 mg	9,305,000	4
Ferrous Sulfate	200 mg folic acid 250mc	8,172,000	10
Benzathine-BP	1.44 g (2.4 MU)	109,022	6
Ciprofloxacin	250 mg	10,900	1 (day)
Determine HIV	Rapid test	No stock card on file	unknown

Source: RMS stock cards, May 2008.

According to the current design, the RMS inventory for any product should be between nine and twelve months of stock. The average of the minimum and maximum stock levels is 9 [$(6 + 12)/2 = 9$]. Considering the already crowded conditions in the RMSs, it is unclear where an RMS would keep nine months of product. This problem is further underscored by the fact that CMS shipments are often held at overflow sites such as the defunct ORS factory, in the storerooms of their customs clearance agent (Allied Shipping), and collecting demurrage charges in port.

Below the RMS there are fairly well detailed procedures for SDP-level and district-level inventory management. SDPs are to hold between two and four months of stock and are resupplied through an allocation system, managed by the DHO. The system was designed to allow districts control over

their health supply budgets and to reduce the effort required for reporting at the SDP level. Data as of the end of March were available for about 60 percent of health centers in Central Region. Of the same eight products, only two were stocked according to plan, five were under-stocked (three critically), and one product was stocked out.

Table 7.2. SDP Stock Status of Essential Medicines (Tracer List SDP Level, Central Region)

Product	Strength	Median Months of Stock at SDPs in Central Region March 2008
Sulphadoxine/P	500/25 mg	1.99
Depo-Provera	150 mg	2.35
Co-trimoxazole	480 mg	1.27
Erythromycin	250 mg	1.43
Ferrous Sulfate	200 mg folic acid 250mc	0.72
Benzathine-BP	1.44 g (2.4 MU)	0.00
Ciprofloxacin	250 mg	0.23
Determine HIV Tests	Rapid test	0.27

Source: *Supply Chain Manager*, April 2008.

\$1.5 million has been allocated from SWAp sources and \$20 million is proposed in the GFATM RCC application for financing to design and construct a new CMS in Lilongwe. This may or may not be constructed on the site of the existing CMS/RMS-Central, but would in any case be a separate warehousing facility. Apart from the support within certain sectors of the GOM and MOH for constructing this facility, a rationale for how it would improve CMS logistics capacity and performance has not been detailed. One consideration is lack of space at the three RMSs, but site visits to RMS-Central and RMS-South in Blantyre indicate that it is poor procurement planning and product selection, rather than space, that is resulting in a number of large-volume, bulky products taking up warehouse space in these facilities.

The team's visit to RMS-Central in Lilongwe concluded that up to 30 percent of the total warehouse space is occupied with (1) expired product; (2) nearly expired product; and (3) overstock of NDCs — all of which are infrequently requisitioned by the DHOs and hospitals. An analysis conducted by the RMS-Central staff at the request of the CMS Director indicated the following:

- The regional store had 22 years worth of stock for Dextrose 50 percent solution, based on historical requisition patterns.
- A large consignment of plaster of Paris (POP) bandages, estimated by the team to occupy ~7 percent of the total warehouse space, expired in May 2008.
- Other products with several years of stock sitting in the warehouse include other NDCs such as disposable surgical facemasks, hypodermic needles, and water for injection solutions — all bulky products, with some set to expire within one year.

A new CMS building may be justified on the grounds that the staff works double duty for CMS and RMS in the Central and Southern Regions. However, overstocking and insufficient personnel can be addressed without the construction of a new storage facility. The risks of adding a new storage tier include:

- May add to the pipeline for essential medicines.

- Will increase storage costs by increasing the number of tiers holding stock from two to three.

A detailed cost-benefit analysis is recommended before any decisions regarding the construction of a new warehouse are considered. Improved procurement planning, multiyear framework contracts, staggered shipments and the removal of expired and unused products from the RMS would likely make a more cost-effective solution to the space issue within the CMS system in the immediate future, and would no doubt lead to improvements in all supply chain management components. The solution, though, is also dependent on the recommended measures taken in these components outlined in this report (e.g., greater quantity demand visibility and product selection decisions through the collection and use of consumption data for procurement decisions).

7.2 RECOMMENDATIONS

The objective to integrate systems that are so different and vital cannot be based simply on a mandate for control. Since there is no immediate threat to sustainability of the ARV management system, the MOH has an opportunity to take control over time while working to build its own capacity. The following recommendations are based on the principle that performance must be maintained even while the MOH takes on increased responsibility for ARV management.

1. **Maintain third party management of the central warehousing and distribution of ARVs in 2009 and 2010.**

- **Rationale**

As has been described in detail above, the MOH uses a centralized model for ARV distribution, which requires both central storage and transport capacity. Storage conditions at the MOH facilities in Lilongwe and Blantyre have a number of critical gaps, including insufficient space (volume) for the existing throughput. This results in cartons being stacked higher than 2.5 meters, crush damage, and risk of physical injury to the personnel. Because there is no location management, the CMS is totally dependent on a small cadre of clerks to identify where in the warehouse products are located. The receipts section has neither the space nor the equipment to properly handle the current throughput. For example, they have no facility for moving pallets and must break bulk for short-term storage. Further, security personnel were not visible to the consultants during site visits at the warehouses. The SDV Malawi Ltd. warehouse, by contrast, offered sufficient, clean and well-organized space for ARV storage in Lilongwe. In addition, the space had visible physical security in the form of security personnel both at the compound gate and within the facility.

Managing an Increased Range and Volume of ART Supplies

Additionally, the complexity of ARV forecasting and distribution is increasing rapidly. New pediatric guidelines recently introduced in Malawi require separate fixed-dose combination (FDC) infant formulations, which, for example, CHAI has been procuring but distributing to only a small number of sites. The new guidelines state that all infants under 12 months of age should be on ART. This will increase procurement volume and expand the number of ART supplies that need to be managed. Additionally, as Malawi's ART program matures, more patients will be switching to alternate first- and second-line therapies. Both of these developments will have the effect of increasing the management burden and cost for forecasting, distribution, and management as a greater variety and number of products have to be handled in relatively small volumes.

2. Shift technical oversight (not operations) of the third party storage/distribution contract for ART from the Third Party Procurement Agent to the CMS after the third-party contracts end in 2010.

- **Rationale**

The HIV/AIDS Unit is currently responsible for distribution planning, but if the responsibility for inventory management is ever to be transferred to CMS, the CMS personnel must begin taking on responsibility whether warehousing is done within a CMS facility or through a 3PL contract. Strengthening linkages between distribution planning (HIV/AIDS Unit), logistics operations (CMS) and execution (3PL contractor) will increase MOH responsibility and control. UNICEF has expressed interest in building MOH capacity in this area, but a specific plan for the next two years has yet to be developed.

3. Make ARV distribution to the ART centers quarterly and use data from quarterly supervisions to improve responsiveness of the distribution.

- **Rationale**

The principal rationale for this recommendation is to link the data collection activity already conducted by the HIV/AIDS Unit to distribution planning on an identical calendar. This can have a number of beneficial effects. First, this will allow the program to establish formal, more stable inventory levels at ART centers from theoretical min/max of 2/8 to a qualified min/max of 3/6. The basis for a three-month minimum at this level is a lead time of two months between the time when a site receives a supervision visit until the time it receives its replenishment, plus one month of buffer stock. The maximum of six months is simply the minimum plus the three-month review period. In both the current scenario and the proposed scenario, the system is a forced ordering allocation. This will also slightly reduce the storage requirements at the ART centers, which are already strained by current volumes. In addition, distribution needs to become both more sensitive and responsive to ART center demand due to the increasing numbers of regimens and anticipated changes in consumption patterns. The risk that increased frequency may cause transport delays should be considered when evaluating transportation resources.

4. Increase and formalize use of central-level storage for ARVs.

- **Rationale**

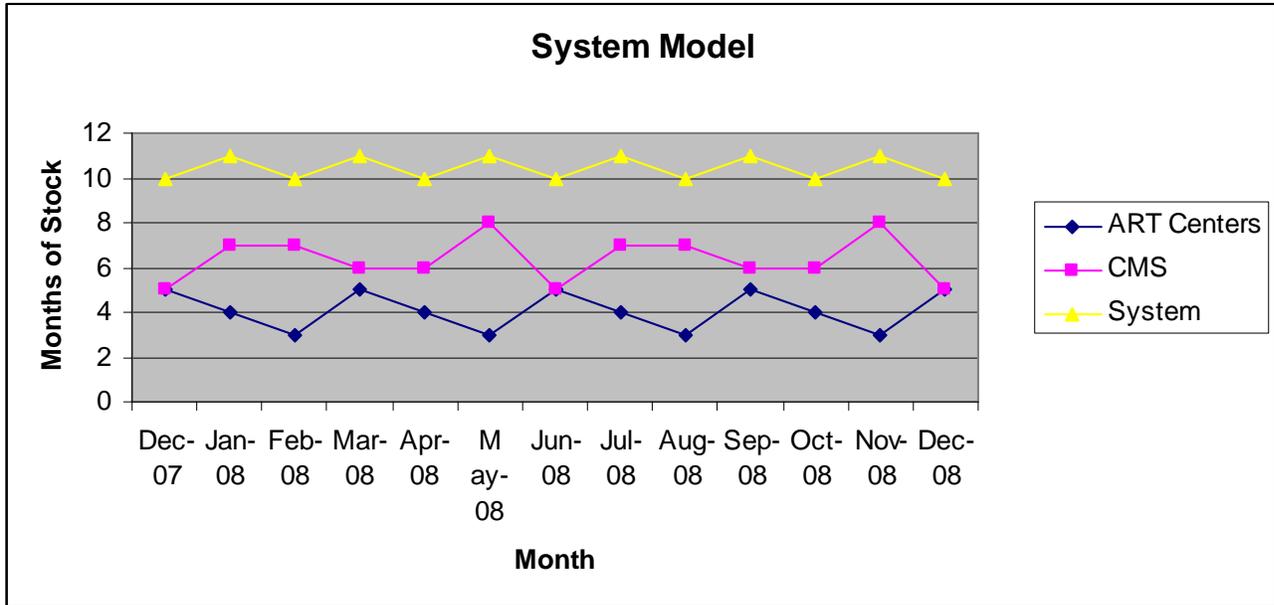
If inventory levels are decreased at the ART centers, this does not necessarily shorten the in-country pipeline in the centralized distribution model. In addition to receiving, break-bulk, assembling shipments and distributing, the central level will need to be able to store goods year-round to respond to ART center demand. This corresponds to the preceding recommendation that some of the storage burden be shifted upstream from the ART centers to the central level.

In addition, we know that the throughput must be either constant or increasing over the next two years; that demand is not stable; and the currently insufficient storage space at 118+ ART centers cannot be scaled up without large capital outlay, whereas, centrally, warehouse space can be leased as needed because 3PL (third party logistics) storage in Lilongwe is flexible.

Central-level inventory levels should be formally established to provide a buffer against uncertainty. The consultant analysis indicated a 9- to 10-month procurement lead time and UNICEF told the consultants that it plans annually around a six-month delivery schedule, whereas SDV informed the consultants that it receives 40 ARV shipments per year. However, none of the informants indicated whether an emergency shipment from their ARV suppliers

would be possible or, if so, what the emergency shipment lead time would be. Therefore, some additional analysis would be required to set central inventory levels.

Figure 7.1. Inventory Volume Model



For the sake of providing an example, if the central store could plan to keep between five and eight months of stock of ARVs on hand and continued to receive shipments on a one- to three-month basis according to an annual shipment plan, and the ART centers maintained between three and six months of stock as proposed, there should always be between 8 and 14 months of stock in the country at any given time. This would support full supply at the ART centers. The system model above assumes the central level receives a shipment of two-month supply of a product every two months and issues a three-month supply to the ART centers every three months. This is what one would expect to see with a high-volume product with limited predictability and some supply uncertainty, such as d4T(30)/3TC/NVP 60-tablet bottles. If demand is highly predictable and suppliers are highly reliable, less total inventory is needed.

The CMS will build a new central facility in Lilongwe within the next two years. The consultants suggest that this new facility take on the role of the receipts section, being responsible for receiving bulk shipments, quarantining shipments during quality control, and allocating and transporting bulk goods to the three RMSs based on a national distribution plan.

Currently, all ARVs come through Lilongwe, but not all essential medicines do. Because the CMS actually receives in Blantyre as well as Lilongwe, and given the conditions at the RMS in Blantyre, one facility in Lilongwe is unlikely to be sufficient for all of their needs. Therefore, the need for a new receipts section to be located somewhere in the Southern region should also be explored.

What role new central-level facilities managed by the CMS would have in ARV warehousing is unclear. The consultants believe that the three RMSs should retain their role of fulfilling SDP requirements, long-term storage, and distribution management, etc. for essential medicines.

When the new facilities are constructed and the organizational responsibilities have been fully defined, the MOH will be better able to consider whether to move warehousing functions for ARVs into the CMS system.

5. Assign a Director for each RMS.

- **Rationale**

In the Central and Southern Regions, general management of RMS functions and receipts section functions both fall under the direction of the Pharmacist-in-Charge, but poor storage conditions in these locations indicate that full-time attention to stores management is required in the RMSs. In general, there are not enough trained personnel to implement current policies. These needs are currently detailed in the organizational development plan for the CMS. Eventual integration of ARVs requires responsiveness that can only be achieved through a well-managed store, and it is the RMS Director's responsibility to ensure that appropriate desk officers, clerks and other staff are in place to implement the RMS warehousing policy and ensure adequate conditions.

8.0 DISTRIBUTION

8.1 FINDINGS AND OBSERVATIONS

There is no overlap between the distribution ARVs and that of essential medicines. SDP distribution decisions for ARVs are made by the HIV/AIDS Unit using the data collected during quarterly supervision visits to plan allocations. SDP distribution of essential medicines is determined by DHOs using monthly reports from the SDPs to plan allocations.

The RMSs transport essential medicines directly to the SDPs but deliver goods for the NGOs to the DHO stores, which then use their own transport resources to pick up from the DHOs. In practice, donated co-trimoxazole and HIV test kits are also mainly delivered to the DHO stores, though standard operating procedures (SOPs) indicate that these products should go directly to health centers from the RMSs. Physical distribution of ARVs is managed by a third party logistics contractor, SDV, whereas physical distribution of essential medicines is managed by the RMSs.

“If you depend on CMS (for your supplies), expect stockouts,” said one ART program manager. ART program staff is satisfied with the high level of stock management service provided by the HIV/AIDS Unit and UNICEF, and were leery of any move toward integration. The HIV/AIDS Unit not only plans the routine distributions made every six months, but is also able to shift stock from overstocked facilities to those at risk of stockout. Maintaining the “push” or allocation system for ART supplies reduces the burden of stock-counting and requisitions preparation from the pharmacy staff, but the HIV/AIDS Unit could not fulfill this planning role without good data. These data come from the quarterly assessment visits made by the HIV/AIDS Unit teams, which requires a substantial investment in time and resources at the central level.

A trial or pilot distribution of co-trimoxazole and HIV test kits by the CMS was initiated in 2007. These products were intended to go directly to the health facilities from the CMS. Instead, the CMS delivered many of the products to DHO stores. However, the DHOs lack vehicle resources for transport from their stores to the health facilities. In addition, the delivery from the CMS/RMS to the DHO stores was itself delayed. The result has been either slow resupply or partially filled orders from the health centers.

The only similarity between the two systems is that they are both allocation systems that deliver goods to SDPs. ARVs are managed by the HIV/AIDS Unit, and essential medicines are managed by the DHO. ARV transport is managed by SDV Malawi Ltd. and essential medicines transport is managed by the RMS. In terms of personnel, transportation resources, scheduling and so forth, the systems are quite different.

8.1.1 ARV SUPPLY MANAGEMENT

ARVs are transported to 118 public health facilities and 45 private sector/NGO facilities. Transportation is provided by UNICEF through a 3PL contract with SDV. UNICEF does not manage each component of the ART supply chain directly. They procure based on order quantities provided by the HIV/AIDS Unit and transport ARVs and other HIV products through a private transport firm (SDV) from a leased warehouse in Lilongwe directly to health centers.

SDV informed the consultant that vehicles in its fleet are less than two years old. By design, resupply frequency is semi-annual, but it may also occur on 4-month and 12-month intervals depending on specific instruction from the HIV/IDS Unit communicated through UNICEF.

According to the N'Dirande Health Center, UNICEF provides quarterly deliveries from SDV. At B'vumbwe, an NGO site, Médecins Sans Frontières (MSF) delivers weekly. There is also no stock status monitoring in the B'vumbwe facility. Stock status is measured in days at the time of visit, as in a delivery truck topping-up system. MSF also uses its own transportation. In theory, ARVs are delivered directly to each ART center individually. In practice, many of the orders are transported to larger facilities, such as major hospitals, and subsequently requisitioned by smaller ART centers.

For example, in Lilongwe ARVs are delivered to the Kamuzu Central Hospital (KCH) stores. The hospital is used as a satellite storage facility for nearby NGO ART centers and the KCH's own outpatient ART program, which all have smaller store rooms. The sites are approximately 1 km or less away, so transportation of ARVs from KCH can be accomplished in a matter of hours. In Dedza, the District Hospital pharmacy stores have been receiving ARVs regularly every six months per the design, but these supplies are used both by the ART center within the District Hospital and also to supply the newly opened Kaphuka health center ART facility. The other two ART sites in Dedza district, MUA and Lobi, receive ART directly from SDV transport contracted by UNICEF.

8.1.2 CMS SUPPLY SYSTEM

At the central level, the CMS has limited visibility on demand and current inventory and therefore cannot adjust product distribution based on RMS issues (based on DHO requests). In the short term, inventory counts and review of issues data from RMSs could help alleviate the bottleneck, but RMSs currently have no way to obtain their own inventory data without a manual stock count and/or review of each stock card in their warehouses. In effect, the lack of data and the subsequent inefficient order planning negates many of the benefits of the two-year framework contracts under which the recent receipts have been arriving.

An RMS may receive two to three in-bound truckloads (7-ton trucks) every other day from the CMS. The RMS, for its part, transports essential medicines directly to the public sector SDPs but delivers goods for the NGOs to the DHO store. Most RMS vehicles are at least five years old, with frequent breakdowns and lack of spare parts. The DHO stores do not formally have their own transport to pick up goods from the RMS or deliver to SDPs. Sometimes vehicles can be borrowed from other programs (e.g., EPI) to transport goods such as HIV rapid tests and co-trimoxazole that have been deposited with them. NGO sites have sidestepped the transportation problem by routinely picking up products from the DHOs.

During the rainy season when the roads are often impassable, the RMS bypasses delivery to SDPs and delivers drugs to DHOs because roads to some of the facilities get washed out and their 7-ton vehicles are unsuitable. DHOs then use smaller vehicles to deliver product to health centers. This happens between November and March, but not all SDPs are affected.

8.2 RECOMMENDATIONS

The general opinion among the stakeholders interviewed is that the MOH decision to support the near-term integration of ART procurement and distribution into the CMS system is premature. Stakeholder interviews indicate that the GOM is concerned with strengthening capacity up and down the supply chain, especially in drug procurement. The stakeholders suggest that a comprehensive distribution assessment would result in a better understanding of the current strengths and challenges within the CMS and point out specific steps to strengthen the system so it could support ART SCM functions. The above findings point to a number of these challenges and strengths, but would need to be further detailed and possibly redesigned to incorporate large volumes of ART products.

Nonetheless, distribution is an area where CMS has some strength, particularly in the short (monthly) resupply period and direct delivery by the RMS to the SDPs. On the other hand, the ARV management system provides a good example of transportation outsourcing. There are distribution lessons to be learned from both programs.

1. Continue vertical distribution of ARVs through a 3PL in the near term.

- **Rationale**

In support of the current centralized distribution model for ARVs, SDV has access to a sufficient number of well-maintained vehicles and routinely accomplishes distribution to all the ART centers in four weeks' time. They maintain good control of receipt information and monitor driver performance, and have been transparent regarding corrective actions involving deliveries. The CMS fleet is aging, and is also occupied with the essential medicines program. Whether these same vehicles could also support the ARV distribution would require additional analysis.

2. Develop a communication policy and tools for the HIV/AIDS Unit to communicate with the ART sites to improve delivery schedules.

- **Rationale**

The stakeholders interviewed and the consultants support the continuing role of the HIV/AIDS Unit in allocating ARVs to the ART centers. The intention would be to further centralize ARV distribution-related inquiries within HIV/AIDS Unit. Also, better advance notice to the ART centers will allow ART center staff to prepare to receive shipment on particular date and time, planning time for off-loading, checking and receipt confirmation at the SDP, thus avoiding disruption to services. Speeding up receiving will also reduce the time a vehicle spends at an SDP, freeing up needed transportation resources.

3. Develop a transportation policy and guidelines – including planning, fleet management, and vehicle replacement and transportation performance metrics, for the CMS. Consider outsourcing.

- **Rationale**

Transportation is a core competency, required to support the CMS inventory management policy. Future integration of ART program product distribution will depend on the CMS either building this capacity within the organization or contracting it out to qualified transportation partners.

Managing transport through 3PL partners can add flexibility and reduce capital costs, but those costs should be compared to building transportation capacity within the CMS.

4. Shift technical oversight of the 3PL contract from UNICEF to the CMS.

- **Rationale**

As was mentioned in Section 7.0, Warehousing and Inventory Control, the CMS personnel must begin taking on responsibility, whether distribution is done with CMS vehicles or through a 3PL contract. Strengthening linkages between distribution planning (HIV/AIDS Unit), logistics operations (CMS), and execution (3PL contractor) will increase MOH responsibility and control. UNICEF has expressed interest in building MOH capacity in this area, but a specific plan for the next two years has yet to be developed. If the MOH decides to move the distribution function to the CMS, they will require a plan that allows the CMS to do some distribution together with a contractor before taking over the responsibility. Alternatively, the CMS may choose to outsource its own transportation. In either case, this should only occur when adequate staffing in CMS has been secured and a strategy for the phased transfer has been agreed-upon by MOH, CMS, UNICEF and health partners.

9.0 LOGISTICS MANAGEMENT INFORMATION SYSTEMS

9.1 FINDINGS AND OBSERVATIONS

At its most basic, the logistics management information system (LMIS) used by a program must support decision making for basic logistics activities such as forecasting and supply management, financial management, warehousing, inventory management, and distribution. The MOH in Malawi is not currently running an enterprise-wide resource planning tool, depending instead on a variety of tools designed to support specific logistics tasks. For example, paper reports are used to collect inventory and consumption data from public sector SDPs, and *Supply Chain Manager* (an Microsoft Access database) is used both to aggregate this data for reporting and to determine resupply quantities for essential medicines.

Figure 9.1. Supply Chain Management Tools

The HIV/AIDS program depends on quarterly supervision visits and paper reports to collect



inventory and consumption and patient data, and Excel spreadsheets to aggregate this data for reporting and to determine resupply quantities for ARVs (i.e., forecasting, quantification, and procurement planning).

In addition to facilitating operations, a good LMIS should also facilitate the monitoring of supply chain management indicators so the program can measure its performance. The examples below, related to distribution and inventory management, are adapted from the AMD Partner Network report “Harmonization of Monitoring and Evaluation Requirements for ARV Procurement and Supply Management Systems” (AMD 2008).

Table 9.1. Sample Distribution and Inventory Management Indicators

Monitoring	Indicator	Required Information	Data Source
Adherence to procedures	Percentage of facilities submitting complete inventory control reports on time according to an established schedule	Number of facilities submitting complete reports on time, total number of facilities in reporting area, reporting deadlines	MOH or CMS reports on reporting schedule, inventory control reports and their submission dates, LMIS
Process performance	Percentage of facilities that received all ARV orders in full and on time	Delivery schedule, required SKUs and quantities, delivered SKUs and quantities	LMIS, ARV receipt reports
System performance/ outputs	Percentage of health facilities dispensing ARVs that have experienced a stockout of one or more ARVs in the last 12 months	Stock levels	LMIS, stock cards and other stock management tools

9.1.1 ARV Supplies Management

The ARV supply management system has particularly good recordkeeping on the forms at the ART center level. Forms include:

1. The Patient Master Card
2. The ART Register
3. Stock Cards

In some hospitals, patient tracking forms are computerized and three different electronic systems have been piloted by different partners. The MOH is planning to use an assessment of these pilots to develop specifications for a computerized patient tracking system which will be implemented nationally in those ART centers that can support the hardware. Smaller, rural sites are likely to continue using paper.

ARV supplies management is also characterized by zero reporting from the ART center level. The ART center keeps records but it is the HIV/AIDS Unit that sends a team every quarter to all of the ART centers and collects (extracts) necessary data during supervision visits. Some of the more organized centers prepare their reports in advance of the supervision visit, but this does not seem to be the norm. Good recordkeeping means that a three-person team can collect all the necessary data in about half a day, provided the consumption and patient data is recorded in the ART Register and Patient Master Cards.

One potential problem for supply data management is that NGO ART sites that draw down on supplies of ART products — which are stored at the DHO pharmacy — do not report inventory or consumption to the DHO pharmacy. These data are eventually captured during the quarterly supervision visit and are available to the HIV/AIDS Unit, but it is problematic for inventory management at the DHO. The DHO exercises some accounting control by requiring a signed order from the District Reproductive Health Program Coordinator before issuing to the NGO, but the DHO pharmacy receives no data with which to justify the issue.

The Coordinator may receive some inventory and consumption information from the NGOs but this is not aggregated in the pharmacy, as it is for all other drugs. This is a problem that must be addressed if the systems are to be integrated in the future.

At the central level, the HIV/AIDS Unit supports its logistics decision making with Excel spreadsheets it created and uses to aggregate the supervision visit data. It also has access to inbound shipment tracking information through UNICEF Copenhagen for UNICEF-procured shipments. For Clinton Foundation-procured shipments, the Clinton procurement team in India operates its own order tracking system.

In addition to the quarterly supervision, some sites (particularly the 10 centers supported by the Clinton Foundation) receive monthly monitoring by phone or fax. These sites have been involved in a pilot program wherein they photograph their ART register and send the Clinton Foundation a digital image. A sentinel survey census in two districts takes place every two years.

As the program is expanding and adding regimens, it is becoming increasingly labor-intensive to manage quarterly supervision out of Lilongwe. There has been some discussion of decentralizing the quarterly supervision to the five health zones, but it is the team's judgment that the existing zonal M&E officers do not have the necessary time and resources to manage and coordinate this activity.

9.1.2 CMS SUPPLY SYSTEM

The CMS supply system has downstream inventory visibility to the SDP level for about 100 products through the *Supply Chain Manager* software in approximately 60 percent of the public sector service delivery points.

As with the ARV supplies management system, NGOs do not report (although an NGO reporting form does exist). Unfortunately, this means that the MOH has no inventory or consumption data for NGOs at present. The principal recording and reporting tools for hospitals and health centers are the stock cards and the LMIS-01 form.

At the district level, the District Pharmacist or Pharmacy Technician inputs the data from the LMIS-01 report into *Supply Chain Manager*. *Supply Chain Manager* then calculates/proposes replenishment quantities for the SDPs for the products reported. *Supply Chain Manager* also aggregates the inventory and consumption data for pipeline monitoring purposes. These data are sent as a paper requisition to the RMS for executing replenishment, and as an electronic file to the CMS for inventory monitoring. There is a plan to begin using *Supply Chain Manager* at the regional level for monitoring adherence to procedures, process performance and system performance/outputs. *Supply Chain Manager* will also have the effect of computerizing the RMS so program managers will know current inventory — data which are currently unattainable without conducting a manual stock count. Regional Logistics Officers have also been hired for each of the three RMSs to perform monitoring and supervision of the LMIS.

The main problem is poor reporting. The CMS/RMS suffers from <50 percent on-time reporting for the public sector sites that report, and some sites do not report at all or they provide incomplete reports. NGOs bypass the system altogether, communicating by cell phone or direct visits. Keeping separate recordkeeping systems for the public sector and NGO sites has contributed to incomplete reporting to and from the DHO store.

At the CMS, there is upstream shipment tracking for both HIV test kits and the RH Program products using *PipeLine* software. Three staff members in the Procurement Department are trained to use *PipeLine*.

There is no functioning warehouse management system (WMS), but *ACCPAC* software is being installed on a wide-area network, and a number of *ACCPAC* ledger modules will eventually capture inventory and issues data in the three RMSs.

Although *ACCPAC* has a WMS module, none of the modules scheduled for implementation as of June 2008 have a warehouse location tracking feature, so some additional paper- or spreadsheet-based system is urgently needed to help management record and identify where in the warehouses different products are located. Currently, this depends on the memories of a cadre of stores clerks.

None of the *ACCPAC* modules scheduled for implementation facilitate downstream inventory monitoring, so *Supply Chain Manager* will have to be maintained in tandem for the foreseeable future. In addition to implementing *ACCPAC*, the MOH is developing a National Stock Status Database (NSSD) to aggregate data from different sources (*Supply Chain Manager*, *ACCPAC*, *PipeLine*, and any NGO reporting system that may be available) to develop a more complete stock picture for their high-priority products.

9.2 RECOMMENDATIONS

1. Inventory available tools and the logistics functions they support and, where possible, link management of operational data to monitoring and evaluation indicators.

• Rationale

Currently, the CMS and the ARV supplies management system are operating in parallel and are managing their data in parallel on different systems. Before any discussion of system integration takes place, managers need to detail key logistics management decisions, including:

- Who makes management decisions in the system
- How frequently decisions are made
- What data are required to make the decisions
- What tools are available for collecting and managing these data

A table of some typical logistics activities and a partial list of how the CMS and the ARV supply system support information management for these activities is attached as Annex 4. Currently, some tasks have tools that support them and others do not. Some tasks have easily identifiable personnel and others do not.

2. **Support rollout of a unified solution for computerization at dispensing windows. Replace the ARV Register where possible, and incorporate an inventory module into the system.**

- **Rationale**

Computerizing dispensing has benefits for both patient flow and monitoring. Touch-screens and bar code menus reduce data entry burden and potential errors at dispensing window and speed up patient transactions, which improves customer service. During supervision visits, patient data and dispensing can be tabulated straight from the database as opposed to being manually calculated from an ART Register.

If the dispensary tool also had a module for the pharmacists to input their monthly inventories, this would allow the ART centers to monitor their own stock status, identify stock problems, and take action before they could affect customer service.

3. **Create a PDA- or laptop-based data collection form for quarterly supervision visits and on-site data entry, and develop a database to aggregate supervision visit data and generate quarterly reports.**

- **Rationale**

The main rationale for this recommendation is to speed up aggregation and development of distribution plans and forecasts based on the quarterly supervision visits. This can reduce lead times and improve responsiveness. In addition, entering the data on-site (or simply uploading it from a dispensary database) will reduce data entry errors.

4. **Introduce *PipeLine* or another appropriate pipeline monitoring and procurement planning tool into the HIV/AIDS Unit for tracking ARV shipments.**

- **Rationale**

Using a tool like *PipeLine* would enable the HIV/AIDS Unit to better plan procurement and timing of inbound shipments and manage their inventory. It would also enable the HIV/AIDS Unit to monitor supplier performance and facilitate communication of program requirements and the status of shipments with stakeholders and partners. However, it was unclear to the team whether it should be the HIV/AIDS Unit in the MOH, or the NAC, that keeps track of procurement and shipments. The team suggests that clarification of who (NAC or MOH) maintains the information and who will be responsible for forecasting, procurement planning and monitoring be conducted as part of the recommendation review process. Currently, the HIV/AIDS Unit manages the supply and patient data. An expansion of this existing responsibility, along with routinely sharing the data with NAC, will help improve in-country stock management and better inform NAC of needed procurement quantities.

5. **The CMS/RMS should roll out *ACCPAC* in the RMS, especially G/L module 4 (Requisition Processing) and Module 9 (Purchase Order). In addition, the CMS/RMS should install *Supply Chain Manager* at the regional level to assist the Regional Logistics Officers to monitor and support district-level order processing.**

- **Rationale**

Strengthening CMS/RMS data management and providing managers with tools and training is a precursor to any future integration of new product categories. The CMS/RMS needs a warehouse management system (WMS) to enable them to track and manage the sixteen hundred products in the three RMS. The functionality of G/L modules 4 and 9 would provide a stop gap measure until the CMS defines its software requirements and determines whether to implement an off-the-shelf solution like the *ACCPAC WMS* module, *Fishbowl*, *Msupply*, *AdvancePro*, *ACCTivate*, *MACS*, etc. or to develop their own WMS solution.

6. **Require the use by NGOs of an equivalent LMIS-01 form with the short list of supplies the NGOs are permitted to draw from the DHO. Require the NGOs to report inventory and consumption regardless of source. Add the NGO facilities to *Supply Chain Manager* as a new category of facility.**

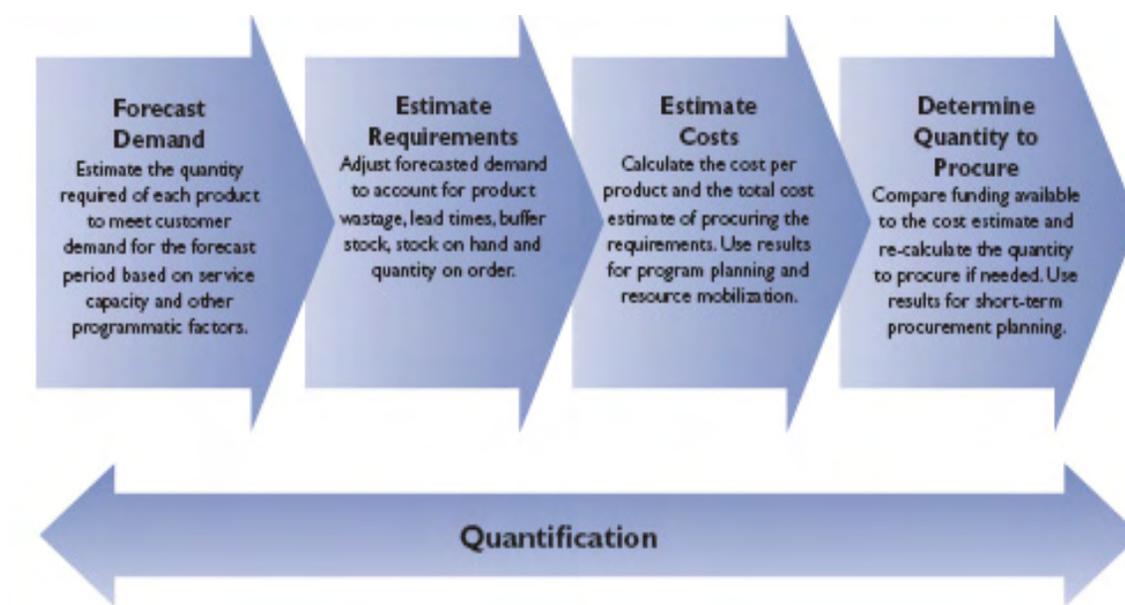
- **Rationale**

Currently there is no visibility into NGO inventory or consumption for products provided for free by the GOM to NGOs, which means that the MOH has no actual understanding of the NGO requirements. This causes problems in inventory management problems, particularly at the DHOs, and forecasting and budgeting problems upstream. In addition, this can be perceived as a lack of transparency and accountability for donated goods. For these reasons, routine reporting needs to be enforced and tied to release of goods, not just to public sector facilities but to the NGOs as well.

10.0 FORECASTING AND QUANTIFICATION

Forecasting demand and quantifying procurement quantities for ARVs, ART products, and other essential medicines is a complex process that is highly dependent on the availability of routine and accurate data. Quantification and forecasting are often mentioned together to describe the general process of estimating necessary product quantities. They are two distinct but related functions. Quantification is generally a post-forecast process that includes estimating the quantities and the cost of products required to meet demand and to fill the pipeline (safety and buffer stock, for example) with adequate quantities.

Figure 10.1. The Forecasting and Quantification Process



Quantification figures will usually be different from the overall forecast because it takes into account service delivery capacity, available warehousing and facility-level storage, and available procurement funds. Quantification (see Figure 10.1) consists of four steps: (1) forecasting demand; (2) estimating requirements; (3) calculating the costs for procuring the requirements; and (4) if needed, adjusting the final quantities to procure according to the amount of funding available. The results of essential medicine quantifications are used (1) to calculate specific order quantities and to plan shipment schedules for short-term procurement planning, and (2) to assist in program planning and to secure financing for the required quantities (Allers and Chandani 2006).

10.1 FINDINGS AND OBSERVATIONS

10.1.1 FORECASTING DEMAND FOR ARVS

ART Patients and Facilities

The HIV/AIDS Unit, together with MOH ART facility staff and NGO partners, collect ART patient and HIV/AIDS commodity data from each of the 163 public and private sites in Malawi on a quarterly basis. The data are not reported by facilities. It is extracted by data collection teams and then used as the basis to conduct semi-annual forecasts and quantifications.

Table 10.1. ART Patient Data, January 2003–December 2007, Public and Private Sector

	By Dec 2003	By Dec 2004	By Dec 2005	By Dec 2006	By Dec 2007
Public sector ART sites	9	24	60	103	118
New patients started ART in year	No data	10,183	24,657	43,981	59,628
Cumulative patients started ART	3,000	13,183	37,840	81,821	141,449
Patients alive on ART	No data	10,761	28,110	57,356	96,712
Private sector ART sites	0	0	23	38	45
New patients started ART in year	0	0	977	2,370	2,060
Cumulative patients started ART	0	0	977	3,347	5,407
Patients alive on ART	0	0	977	2,624	3,937
Public and private ART sites	9	24	83	141	163
New patients started ART in year	No data	10,183	25,634	46,351	61,688
Cumulative patients started ART	3,000	13,183	38,817	85,168	146,856
Patients alive on ART	No data	10,761	29,087	59,980	100,649

As of the beginning of January 2008, there are 118 public sector and NGO sites and 45 private facilities conducting ART. The number of cumulative patients ever started on ART from January 2003 through December 2007 is 146,856, with 100,649 currently alive on ART (MMOH, 2008). Ninety-six percent of all patients are on standard first-line therapy, with the remaining on alternate first-line and approximately 2 percent on second-line ART. Eight percent of those ever started on ART are age 14 and under.

From December 2004 through December 2007, ART patient scale-up has increased more than 1,000 percent. From 2005 to 2006 the program saw nearly a 100 percent increase in patients, and between 2006 and 2007 patient numbers grew by more than 60 percent to the more than 100,000 currently on ART. Despite the recent, relative slowdown in growth rates (if just in comparison to the enormous growth rates in early years), the number of patients and volume of ARVs and related pharmaceuticals to treat side effects and OIs and maintain efficacy continues to grow year-over-year. This will make forecasting and quantification more challenging, not only because of the increased volume of product but also because many existing patients will begin to shift therapies. The program is expected to grow to more than 316,000 patients by 2013 (CCM, NAC, MMOH 2007).

ART FORECASTING

Forecasting is conducted as a joint exercise within the HIV/AIDS Unit and is supported by partners involved in the quarterly data collection. The semi-annual exercises are based on:

1. The number of existing patients on each of the six possible regimens (two-week starter pack for new patients; standard first-line (Triomune 30); three alternate first-line therapies, and one second-line therapy).
2. The number of new patients enrolled in each of the sites during the previous quarter and regimen type (97 percent standard first-line).
3. Estimate of new patients for next two quarters using previous two quarters' data.
4. Use of Patient Master Cards and cohort analysis to determine previous and estimated switching rate to second-line and alternate first-line therapies.

The HIV/AIDS Unit developed a checklist of data that are collected by the teams. The data used to make the initial forecasts include:

- **ART Register and Patient Master Card:** Number of new patients, number of existing patients, and regimen of each patient.
- **ARV Drug Register:** A log book that identifies patients by number and records dispensing quantities for each patient. It is used for random cross-checks with the stock count in the pharmacy.
- **Stores Inventory:** Determine consumption and cross-check the ART Register and ARV Drug Register by subtracting the number of products delivered in last order by the number of products in stock.

An electronic touch-screen system is operated in 12 of the 160 ART facilities. Data are captured by automated systems in some of the larger district-based hospitals and NGOs by using a hand-held bar code scanner which scans product bar codes at the dispensing window and allows electronic entry of patient data. The 12 automated sites include a patchwork of different systems set up by a

Source Data for Forecasting: Lighthouse Clinic, Lilongwe

Stock management is conducted here the same it is at other NGO and most MOH government ART sites. They use an ARV Register to record consumption, Patient Master Cards to record side effects, treatment outcomes, and other health statistics, and (unlike the smaller MOH ART facilities) use an electronic touch-screen patient management system. The information management system at Lighthouse is also linked to the “scale station.” Patient weight is digitally recorded in the system and then ARV dosage is instantly calculated, which then appears on the touch-screen system used by the dispensing pharmacist. Further, if patients return for their next appointment with a number of pills above a certain threshold, or have “lost” large quantities of pills, those figures are entered into the system and a prompt is then displayed on the screen stating, “...needs adherence counseling.”

number of donors and technical assistance agencies. Further, from what the team was told, there currently is no module in the Baobab system — used by four of the major sites — to run consumption reports, though the data are in the system. The potential advantage of the automated systems is that once the software module is developed to run consumption reports, the hand-written ARV Drug Register can be possibly

discarded in the computerized sites, saving time for clinical staff already stretched thin by multiple duties. The Register will need to continue to be used until it is clear that the computerized system captures all of the necessary data. Also, not all sites are, or will be in the near future, ready for automation because of lack of infrastructure and sufficiently trained staff, so the Register will continue to be important.

Current inventory in each facility is used to make supply quantity distribution decisions. However, through discussions with the HIV/AIDS Unit it does not appear that consumption quantities are used to develop the six-month forecast quantities. Instead, as described above, the number of existing patients, estimated new patients, regimen type, and switching rate data and assumptions are used to calculate needs and eventual order quantities.

ARV QUANTIFICATION

The HIV/AIDS Unit, working with UNICEF, uses the patient data and current stock on hand as the basis for the quantification. Once estimated patients, new patients, existing patients, and switching rates have been established (using the previous two quarters' data to make those assumptions), the figures are then multiplied by the product regimens for each expected patient for six months, and then two months' buffer stock is added to that total.

The original forecasting and quantification process was based on a six- to seven-month lead time. The HIV/AIDS Unit conducted semi-annual quantifications and procurement planning with UNICEF in April and October of each year. Following approvals by NAC — the principal recipient of the GFATM ARV funding, and disbursement by GFATM's Local Funds Agent (LFA) to UNICEF's procurement account — products were expected to arrive in October. The cycle would then repeat itself on a semi-annual basis. They have built a two-month buffer stock into the order quantities by simply ensuring the stock arrives two months before the quantification indicates they would be needed, effectively making it a two-month min/eight-month max system at the ART center level and a pass-through at a central level that, theoretically, holds no inventory.

In practice, procurement lead times have increased to 10 months. If the current policy of pushing the entire inventory to the ART centers would be maintained, an additional four months of stock would need to be added to maintain two months of buffer stock because lead times have gone up from approximately 6–7 to 10 months, and the interval between replenishments would also be increased. The assumptions used in the quantification process would need to be modified to account for this by quantifying for and ordering 12 months of stock and replenishments would have to be planned for every 10 months. The 8/2 max/min system would need to be modified to a 10/2 system to ensure stock on hand at the ART sites. Based on observations of a limited number of ART sites, interviews with pharmacists, and planned patient scale-up, the majority of sites may not be able to hold 10 months of stock at current patient numbers without expanding stores space.

However, the ART center inventory and replenishment period does not need to depend directly on the procurement lead time if delivery intervals to sites can be increased and stock is maintained at the central level. In addition, the central level does not actually receive commodities in two large shipments, but in 40 smaller shipments that are somewhat dispersed. If the central level could keep between five and eight months of stock of ARVs on hand and plan to receive shipments on a three-month basis according to an

The ART center inventory and replenishment period does not need to depend directly on the procurement lead time if delivery intervals to sites can be increased and stock is maintained at the central level.

annual shipment plan, and the ART centers maintained between three and six months of stock, there should always be between 8 and 14 months of stock in the country at any given time, which addresses the lead time issue and supports full supply at the ART centers. The consultants recommend establishing a central level storage tier, modifying SDV's TOR to include maintaining inventory in Lilongwe and providing smaller, quarterly replenishments to the ART centers (see Section 7.0, Recommendation 3).

10.1.2 Forecasting and Quantification: CMS Essential Medicines

The CMS manages integrated logistics systems of several categories and types of products. There are currently 1,557 pharmaceuticals and non-drug consumables in the CMS catalog of products. These products are categorized by formulary (e.g., tablets and capsules) and use (e.g., dental items, and laboratory equipment) rather than by vital, essential, or non-essential. One thousand seventy-five of these products have been entered into copies of the *Supply Chain Manager* database at the DHOs, and plans are also underway to both install *Supply Chain Manager* at the RMS/CMS and enter each of the catalog products in the database.

The central challenge in conducting logistics based forecasts is simply that much of the data for the 1,557 CMS catalog products is not recorded at the facility level and does not get routinely disseminated from facilities to the DHOs and then to the CMS. The second challenge is one of priorities. As discussed earlier, there is no policy in place that links which EHP products should be in full supply with efforts to capture logistics data for those products in the CMS system. A recent forecasting exercise was organized by the CMS with support from the USAID | DELIVER to help inform quantity amounts for the next two-year CMS procurement. The decision was quickly made that it would not be possible to conduct a separate forecast for each of the 1,557 products because there were no logistics data, morbidity data, or any other type of statistical data available to determine demand or order quantities. In addition, many of the catalog products are rarely requested by DHOs or hospitals. Subsequently, CMS developed a list of 241 pharmaceuticals and consumables for the forecasting exercise, based partially on requisition data and anecdotal evidence of demand from DHOs and hospitals. Many of the products are on both the Malawi Essential Medicines List (MEML) and the WHO Model Essential Medicines List. They included albendazole, dextrose, doxycyclin, a number of contraceptives, and so on. After looking at the available data, the USAID | DELIVER Project and CMS concluded that it was only possible to conduct a forecast for 217 of the 1,557 products in the CMS catalog because it was for these products that logistics and morbidity data, though not entirely accurate, were available.

The forecasting exercise for the 217 products was conducted over a two-week period. It covered a two-year period consistent with the CMS two-year framework procurement it recently developed.

The process was as follows:

1. Conducted a physical inventory count of all health centers, which involved MOH staff, USAID | DELIVER technical staff, pharmacy technicians and staff from the DHTSS and RMS. The physical inventory was required because the *Supply Chain Manager* databases were not updated at many of the DHOs.
2. Examined consumption and issues data for each of the 217 products that were available from DHO databases.

3. Supplemented the data collection with morbidity data and population data where it was not possible to determine consumption with only the logistics data.
4. Used data from 2005 and 2006 that was collected previously to make assumptions about future demand.
5. Following data collection, the CMS team and partners consulted clinicians regarding the accuracy and use of the morbidity data. There were several clinical opinions expressed during the exercise regarding the accuracy of the data.
6. Divided the products into two sets: one set was the products quantified using logistics data; the other was the set of “unsure” products for which morbidity data was used to forecast demand.
7. Following an agreement on the numbers among team members, unit prices from the 2005 MSH Price Indicator Guide were used to develop cost estimates for a two-year supply of each of the 217 products.

The CMS now plans to conduct annual forecasts for a yet to be determined proportion of the products in the CMS catalog. It is clear that the products it selects for forecasting and procurement planning should be associated with the essential medicines list, vital products for each level of health facilities (e.g., health posts and hospitals), and related to the products needed for EHP services. Further, a subset of 40 products were selected from the list of 217 that will be used as a set of “tracer products” that the CMS and partners should maintain in full supply and will act as a proxy for the overall level of service of the system.

Following the establishment of the forecast quantities, CMS determines available SWAp procurement funds, GOM resources, and product donations to determine procurement quantities.

10.2 RECOMMENDATIONS: FORECASTING

ART

1. Review and revise assumptions of the ARV quantification methodology.

- **Rationale**
 - Original lead times were estimated at six months between quantification and delivery of ARVs to health facilities.
 - Two-month safety stock was included in this assumption.
 - Total maximum stock levels were eight months at ART facility level ($6/m + 2/m = 8/m$ max).
 - The assumption was that there would be no central-level holding stock, only a trans-shipment facility where products would be repackaged and distributed to facilities (approximately two weeks).
 - Lead times between quantification and distribution to facilities has increased to 10 months (see figure 6.2 in the procurement section).

- Based on new lead times, the time interval used to forecast and quantify delivery volumes to ART centers would have to be expanded, or there will be a need to maintain central-level stock to resupply facilities and ensure adequate buffer stock.
- Currently, resupply to ART sites will not be possible every six months when it takes 10 months to resupply facilities if no stock is held at the central level. In theory, there would be no stock available to resupply because of the two-month difference between max stock levels and lead times $8 - 10 = (-2)$.

2. Maintain central-level stock to address longer lead times and switch to a quarterly delivery system to minimize facility-level holdings.

• Rationale

- Given the increasing numbers of ART patients at each site, it will not be possible for these facilities to store the maximum of 12 months stock (10/m lead time + 2/m safety stock) if all stock is maintained at the facility level.
- Central-level stock maintenance will address the longer lead times and provide stock for quarterly deliveries. As a result, stock levels at the facility level can be changed to max 6/m and min 3/m (quarterly deliveries will bring max up to 6/m at the facility level, decreasing current max by two months).
- Central-level stock should therefore be max 8/m and min 5/m. The total in-country *PipeLine* would be a min of 8/m of stock and a max of 14/m of stock, which should address the lead time issue and the need for additional buffer. Shipments to the central level can then be rationalized depending on volume and spread over the course of the year.
- Inventory level proposals should be further discussed with a system design team.

3. Coordinate ARV forecasting with proposed CMS quantification team structure.

• Rationale

- Coordination of forecasting and quantification process with other programs will allow for sharing and improvements of methodologies among the quantification teams and serve as an entrée toward potential integration of ARV data management and analysis with the CMS structure.

Essential Medicines

1. Revise quantification team structure so it is consistent with the EHP service pillars.

• Rationale

- The focus of the CMS procurement and supply chain should be the essential medicines and consumables directly associated with the standard treatment guides (STGs) in the EHP.
- Each EHP service pillar should be included in the form of a quantification team (See Figure 6.4). Overlap already exists (e.g., HIV, malaria, and family planning). However, a comprehensive, formalized structure will help ensure that consumption data are available for the data management, procurement and distribution of the “essential of the essential” medicines. Formalized forecasting/quantification teams in line with the EHP of services would also provide a useful delineation for drug budget and order quantity decisions made

by CMS and policy makers, highlighting the key products that must be in full supply to meet EHP objectives and, thus, the broader goals of the Malawi POW and SWAp.

11.0 CONCLUSIONS

11.1 MAIN OBSERVATIONS

1. CMS and related public sector agencies do not currently possess adequate technical, organizational, or infrastructural capacity to integrate procurement, inventory control, distribution, and data management of ARVs without compromising the current quality of service.
2. These functions should remain vertical until capacity is developed to carry out the PSM activities on behalf of the MOH's ART program.
3. Transforming the CMS into a trust is the catalyst from which HR capacity can be improved (and sustained) and other reforms implemented.
4. CMS has made significant improvements in data management and distribution.
5. The HIV/AIDS Unit is providing a high level of service by (1) collecting and managing logistics and patient data, and (2) forecasting demand and quantifying procurement.
6. The recommendations help chart a course to (1) maintain and improve quality of service of ART provision, and (2) detail capacity-building measures within the CMS and other agencies to phase-in integration over time, subject to improvements in performance.

11.2 PSM INDICATORS

The recommendations, if accepted and acted upon, will also need to be monitored and evaluated to determine efficacy, help determine remedial action (if any), and inform the MOH and donor partners on progress. The AMD Partner Network has recently developed a set of 12 core and 30 supplementary indicators to measure the performance of ARV PSM systems (AMD 2008). The basis for the indicators was the noted absence of coordinated, harmonized and relevant M&E indicators to track PSM performance of ART programs. The WHO/AMD lead team found that different indicators were used for similar programs across a number of countries. Subsequently, there was (is) a need to harmonize PSM indicators to make M&E more comparable across programs, as well to make sure the data needed to measure PSM performance was either easily accessible or already routinely collected.

As of this writing, the indicators are still in draft form. However, after review of the core and supplementary indicators, the consultant team concluded that there was an acceptable degree of correlation between the recommendations in this report and many of the core and supplementary indicators. We expect the indicators to be a practical tool for program managers in charge of planning, management, implementation, monitoring and reporting on Malawi's ART program. The

inclusion of these indicators may also be in line with GFATM's expectation regarding reporting for the Rolling Continuation Channel (RCC).

The consultant team suggests that the workplan developed as a result of this report, or as part of a larger effort to improve PSM across programs, should include the AMD Network Harmonized indicators. Two indicators have been chosen from the AMD Network's M&E draft document that corresponds most closely to the PSM components used as the framework for this report: "Proportion of ARV Orders Done while the ARV Stock Level On Hand Is within the Minimum Stock Level during the Last 12 Months" and "Percentage of Health Facilities Dispensing ARVs that Have Experienced a Stockout of One or More ARVs in the Last 12 Months". The indicators are included in the timeline tables below and are indicated as either "core" or "supplementary," consistent with designation in the AMD draft document.

11.3 IMPLEMENTING THE RECOMMENDATIONS

- Both the Technical Working Group for Medicines and the Health and HIV SWAp pool partners working together will need to determine which recommendations among those listed in this report they will accept. The expectation is that the MOH will take on the leadership, with support from the Health Donor Group, to view the recommendations within the supply chain operating context in Malawi and other existing PSM strategies and plans.
- Following that, the recommendation to create a permanent PSM directorate (coordinating office) will be a critical first step toward marshalling the political will and momentum to develop a workplan. However, an interim coordinating body (a reinvigorated Medical Supplies TWG, perhaps) should be assembled to select or discard the recommendations in this report and develop a broad PSM workplan that encompasses the selected recommendations and other PSM strategies not covered in this consultancy's terms of reference. The findings/recommendations in this report should be combined with existing strategies and reform proposals [e.g., CMS Reforms Proposal, which is currently in implementation; PSM categories in the MOH Program of Work (POW), and the workplan associated with the GFATM RCC grant]. Many of the findings and recommendations in this report overlap with the objectives, and in some cases, specific activities of these existing plans. The challenge will be to integrate, prioritize, and implement the numerous proposals recommended by these different analyses. The level of detail required for such a workplan is beyond the scope of this activity and cannot be developed until the recommendations have been discussed, accepted, rejected, or revised.
- Each recommendation will require a commitment to a series of specific steps addressing the gaps identified in the "Findings and Observations" and "Rationale" sections of each chapter. In a few instances, the consultant team has suggested, as a recommendation, that no action be taken (e.g., do not embark on a specific course of action). These would naturally require more of a decision and less of process. The most suitable example of this is the broad conclusion of this report stated in Section 1.0: "Integration of procurement, inventory control, distribution, and forecasting/logistics data management¹⁵ of ARVs (for the ART program) is not recommended

¹⁵ Logistics and patient data collection, forecasting, and quantification are functions currently managed by the MOH through the HIV/AIDS Unit. It can be suggested that these functions are already "integrated" into the public sector. A more orthodox definition may conclude that these functions must be integrated within the CMS management information systems. The recommendation is to maintain that function with the HIV/AIDS Unit. The rationale for this recommendation is detailed in Section 9.0, LMIS. This is principally because patient data are needed for ARV forecasting and quantification, which is not collected in the CMS LMIS. Further, it is the consultant team's position that the quarterly ART site monitoring and data extraction is serving the program well and should not be changed, despite concerns regarding program expansion and sustainability.

at this time.” Of course, to eventually achieve that integration, this report has laid out a series of specific recommendations which suggests, simply, what actions will lead to improved capacity in these three and the other PSM-related functions necessary for ART programming — human resources, financing, and policy implementation, which cuts across each of the PSM functions.

- The suggested timeframe for the implementation of the initial recommendations in this report is from July 2008 through December 2010. There was discussion, then consensus among the consultant team regarding the time period for the recommendations. Given the urgency of maintaining the quality of service for the ART program and improving the capacity of the CMS essential drug system (and ART program), the team felt the suggested action should be focused on near-term (two to three years) improvements. Beyond that period, immediate steps recommended may become somewhat generalized and non-specific, perhaps best suited for longer-term strategic planning. Nonetheless, within the implementation timeframe in each PSM category, both short-term (i.e., second half of 2008 and first half of 2009) and medium-term (second half of 2009 through 2010) recommendations have been developed by the team’s estimation of what both needs and can be accomplished during this time period.
- The following tables provide an initial implementation timetable template and indicate the organization that might be best placed to manage each recommendation/activity. Only the key, select recommendations from the report are used in the tables simply as a way to illustrate the next steps that need to be taken. It is not a substitution for a workplan, but a way to frame the recommendations that are accepted and help begin the work planning process.

11.3.1 TIMELINE TABLES

The following tables were developed on the recommendation of the stakeholder group members who participated in the presentation of the team’s initial findings in Lilongwe on June 6, 2008. Only key, recommended actions are included for each component so as to avoid repeating these points detailed in the body of the report. The intent of the timeline tables is to provide a PSM coordinating group with some initial guidance regarding which organization may be positioned to take the lead role in implementation. The recommendations and initial guidance are also intended to support a subsequent PSM work planning process.

The proposed indicator in each component does not directly correspond to each of the recommendations. Rather, it would provide a broad measure of performance for each of the PSM functions. Consequently, the proposed work planning process would require one specific indicator for each of the accepted recommendations.

Implementation Timeframe: Policy Context													
Performance Indicator: None Available in AMD Harmonization Document													
Recommended Actions	Organization	2008				2009				2010			
		1	2	3	4	1	2	3	4	1	2	3	4
1. Dissolve the current Medical Supplies Technical Working Group and replace it with a separately created office charged with oversight of all public, donor, and NGO sector PSM initiatives in Malawi.	DHTSS; HDG												
2. Implement the consensus policy position and direction to move CMS from a GOM Treasury unit to an independent trust.	DHTSS; HDG												
3. Assemble for a multiday workshop to align product selection, procurement, and distribution decisions of health products with the EHP.	CMS; USAID DELIVER; EHP clinical partners												
Implementation Timeframe: Financing													
Performance Indicator: A National Consolidated Procurement Plan Exists and Has Been Approved/Funded by All Partners (Supplementary Indicator)													
Recommended Actions	Organization	2008				2009				2010			
		1	2	3	4	1	2	3	4	1	2	3	4
1. Conduct a long-term forecast (six years) of projected ARV demand to determine estimated budget during the GFATM RCC grant period.	HIV/AIDS Unit												
2. Re-examine the 12 percent and 5 percent fee structure in view of actual costs procurement and distribution costs.	CMS; DHTSS												
3. Increase the amount DHOs and hospitals can spend on private sector commodity purchases from 30 percent of their total drug budget to 60 percent.	DHTSS; MOF; CMS												
Implementation Timeframe: Procurement													
Performance Indicator: Percentage of Non-Emergency (Regular) Orders Delivered In Full and On Time as Stated in the Procurement Agreement in the Last 12 Months for Each Supplier (Core Indicator)													
Recommended Actions	Organization	2008				2009				2010			
		1	2	3	4	1	2	3	4	1	2	3	4
1. Maintain ARV procurement vertical to the CMS logistics system.	GOM; HDG												
2. Select and bundle (services) private sector third party agent to (1) conduct ART procurement, and (2) build the requisite procurement management and technical capacity for a range of ART products and essential medicines.	CMS; DHTSS												
3. Decrease lead times within the ART and CMS-managed essential medicines system.	HIV/AIDS UNIT; TPPA;												

	CMS																		
Implementation Timeframe: Warehousing/Inventory Control																			
Performance Indicator: Percentage of Facilities Submitting Complete Inventory Control Reports On Time According to an Established Schedule (Core Indicator)																			
Recommended Actions	Organization	2008				2009				2010									
		1	2	3	4	1	2	3	4	1	2	3	4						
1. Make ARV distribution to the ART centers quarterly and use data from quarterly supervisions to improve responsiveness of the distribution.	HIV/AIDS Unit																		
2. Maintain third party management of the central warehousing and distribution of ARVs in 2009 and 2010.	MOH; DHTSS; GFATM; NAC; CMS																		
3. Increase use of central-level storage for ARVs.	CMS; NAC; GFATM																		
Implementation Timeframe: LMIS																			
Performance Indicator: Proportion of ARV Orders Done while the ARV Stock Level On Hand Is within the Minimum Stock Level during the Last 12 Months (Core Indicator)¹⁶																			
Recommended Actions	Organization	2008				2009				2010									
		1	2	3	4	1	2	3	4	1	2	3	4						
1. Introduce <i>PipeLine</i> or other appropriate pipeline monitoring and procurement planning tool into the HIV/AIDS Unit for tracking ARV shipments.	HIV/AIDS Unit																		
2. Support rollout of unified solution for computerization at dispensing windows; replace the ARV register where possible; incorporate an inventory module into the system.	HIV/AIDS Unit; MOH																		
3. Require the use by NGOs of an equivalent LMIS-01 form with the short list of supplies the NGOs are permitted to draw from the DHO.	MOH; CMS; NGOs (dispensing ART)																		
Implementation Timeframe: Forecasting																			
Performance Indicator: Percentage Variation between (1) Consumed Quantities, and (2) Supplied Quantities Minus Planned Buffer Stock (Second-Level Core Indicator)¹⁷																			
Recommended Actions	Organization	2008				2009				2010									
		1	2	3	4	1	2	3	4	1	2	3	4						
1. Coordinate ARV forecasting with proposed CMS quantification team structure.	HIV/AIDS Unit; CMS; USAID DELIVER																		
2. Review and revise assumptions of the ARV forecasting	HIV/AIDS																		

¹⁶ This indicator is categorized under "Availability" in the AMD Harmonized M&E Indicators document.

¹⁷ Accounting for buffer stock was added by the consultant team.

methodology.	Unit; USAID DELIVER																		
3. Revise quantification team structure so it is consistent with the EHP service pillars.	MOH; HDG; NDRA;																		
Implementation Timeframe: Distribution																			
Performance Indicator: Percentage of Health Facilities Dispensing ARVs that Have Experienced a Stockout of One or More ARVs in the Last 12 Months (Core Indicator)¹⁸																			
Recommended Actions	Organization	2008				2009				2010									
		1	2	3	4	1	2	3	4	1	2	3	4						
1. Continue vertical distribution of ARVs through a 3PL in the near term.	NAC; GFATM; TPPA																		
2. Develop a transportation policy and guidelines, including transportation planning, fleet management, and vehicle replacement and transportation performance metrics for the CMS. Consider outsourcing.	DHTSS; CMS																		
3. Develop a communication policy and tools for the HIV/AIDS Unit to communicate with the ART sites to improve delivery schedules.	HIV/AIDS Unit; ART site programs																		

¹⁸ This indicator is categorized under "Availability" in the AMD Harmonized M&E Indicators document.

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ANNEXES

ANNEX I — AGENDA: INITIAL STAKEHOLDER WORKSHOP

May 27, 2008

Workshop Objectives

1. Present the assessment methodology to stakeholders.
2. Receive feedback from key technical informants and policy-level stakeholders on the methodology.
3. Obtain input on the supply chain strengths, weaknesses and potential actions for both the ART and the CMS essential medicines distribution systems.
4. Establish contacts with stakeholders for follow-up interviews and data collection.

ACTIVITY/TOPIC	TIME
Opening Remarks by Chair	9:00–9:10
Self Introduction of Participants	9:10–9:15
Remarks by MOH, UNICEF, DELIVER, others	9:10–9:20
Presentation of Methodology (Parts I & II) Participant feedback	9:20–10:30
Coffee/Tea Break	10:30–10:45
Presentation of Group Work Guidance	10:45–11:00
Group Work Session I Strengths and gaps in current supply chains	11:00–12:00
Plenary Discussion	12:00–1:00
Lunch	1:00–2:00
Group Work Session II Potential actions to address gaps	2:00–3:00
Plenary Discussion	3:00–4:00

Final Thoughts/Next Steps	4:00–4:15
Closing Remarks and Conclusion	4:15–4:30

Expected Outputs

- Consensus on methodology.
- Consultants understand key supply chain strengths and weaknesses of each system.
- Agreement, and possible dates, established for follow-on key informant interviews.

ANNEX 2 — PROGRAM-BASED INTERVIEWS

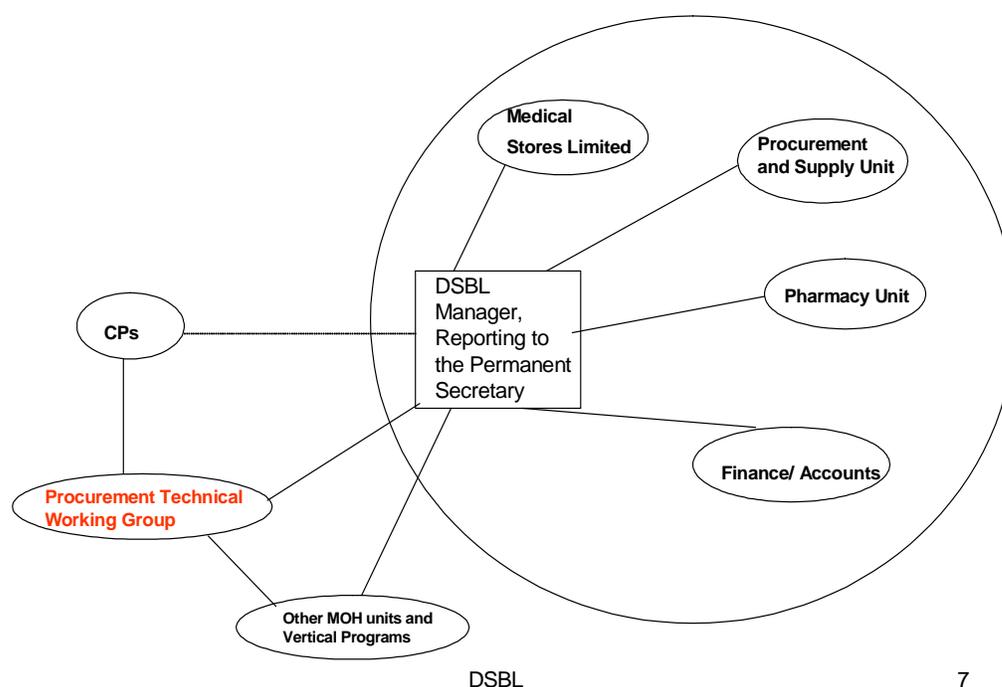
Name (n = 19)	Organization	Location	Position
Anita S. Deshpande	Clinton Foundation	Quincy, MA	Supply Chain Analyst
Caesar Munondo	UNICEF	Lilongwe	Procurement Officer
Chiefundo Gundaphiri	Central Region–RMS	Lilongwe	Pharmacist-in-Charge
Christine Phiri	CMS	Lilongwe	Chief Pharmacist
Dai Ellis	Clinton Foundation	Quincy, MA	Executive Vice President
Darlington Mtupa	CMS	Lilongwe	Principal Procurement Officer
Ejaz Girach	Gestetner NCR	Blantyre	Systems Engineer
Emily Hughes	USAID/Malawi	Lilongwe	Program Manager
Erik Schouten	HIV/AIDS Unit	Lilongwe	Coordinator
Francis Chafulumira	DHTSS	Lilongwe	Deputy Director
Grace Chimowa	CMS	Lilongwe	IT Officer
Ivy Zingano	CMS	Lilongwe	Director
Jayne Waweru	USAID DELIVER	Lilongwe	Resident Advisor
Leonard L.D. Mdechi	SDV Malawi, Ltd.	Lilongwe	Assistant Branch Manager
Louis	HTSS	Lilongwe	Deputy Director
Paula Ghrist	LFA for GFATM	Lilongwe	LFA Consultant
Peter B.S. Ellis	Clinton Foundation	Lilongwe	Director of Health
Simon Makombe	HIV/AIDS Unit	Lilongwe	HIV/AIDS Coordinator
Veronica Chipeta	Clinton Foundation	Lilongwe	Malaria Program Officer

ANNEX 3 — ILLUSTRATIVE TERMS OF REFERENCE (TOR) FOR ZAMBIA DRUG SUPPLY BUDGET LINE OFFICE (DSBL)

➤ Rationale

- A wide range of uncoordinated administrative, operational and policy arrangements resulted in inefficient procurement and supply activities.
- There was an increasing demand from the public, government and donors for a major shift in practices related to procurement and supply chain management, specifically for essential drugs and medical supplies
- Donors and Ministry of Health (MOH) collaborated to address these problems.

The DSBL Secretariat: Liaison, Coordinating, Supporting and Action



- A proposed solution was to establish a platform, the Drug Supply Budget Line Office (DSBL) at MOH through which MOH, and other stakeholders could address concerns as well as drive solutions for improvements.
- The role of the DSBL is to coordinate, liaise, facilitate, monitor, report on transactions and services, and (together with partners) support the establishment of efficient procurement and supply chain management.
 - DSBL is a commitment taken by MOH and CPs to increase access to essential medical products.

Operations

- Commitment of MOH shown by DSBL reporting direct to the Permanent Secretary (PS).
- The DSBL Secretariat meets once a week at Medical Stores, Ltd. (MSL).
- Within MOH, activities are coordinated under a “round table” framework.
- “Round table” extends to meetings with key stakeholders.
- Coordinates with key stakeholders and partners in procurement and supply management (PSM).
- Support activities of these stakeholders and partners.
- Jointly address areas decreasing efficiency in procurement supply chain, and reducing commodity security.
- DSBL and Procurement and Supply Unit meets with the Procurement Technical Working Group every two weeks at MSL to brief on transactions and related decisions, channel request for CP support on system change issues.
- Human resource issues that impact on PSM, and including recommendations to respective offices through the PS’s office.
- Procurement planning mechanisms and review.
- Procurement strategies and review.
- Financing issues that have impact on PSM.
- Supporting capacity-building to firm compliance to rules and regulations.
- Promote transparency and accountability in all operational areas.

ANNEX 4 — SUPPLY MANAGEMENT TOOLS

Supply Management-Related Tasks	Responsible	Key Data	Tools / CMS Essential Medicines	Tools / ART Program
ACCOUNTING-RELATED				
Budget Management	Program officers, Accounts Dept.	Funding sources, allocations, disbursements by allocation, reporting policy	ACCPAC	
Invoice Management	Accounts Dept.	Invoice/PO numbers, approvals policy	ACCPAC	
Accounts Receivable	Accounts Dept.	Customer list, invoice/PO numbers, invoice values	ACCPAC	
Accounts Payable	Accounts Dept.	Supplier list, invoice/PO numbers, PO values	ACCPAC	
Monitoring Payment Cycle Time	Office of the Director Accounts Dept.	Invoice/PO numbers, date invoice/PO received, date approved Date Payment		
PROCUREMENT-RELATED				
Forecasting	Program officers	Selected products, historical consumption, demographic projections, numbers of patients served, patients by regimen and weight band	Spreadsheets	Spreadsheets
Quantification	Program officers, Procurement Dept.	Forecasts, stock on hand, projected losses and adjustments	PipeLine	
Procurement Planning	Program officers, Procurement Dept.	Quantification, supplier lead times, frequency of shipments, min/max levels	PipeLine	
Preparing Tender Documents	Procurement Dept.	Product specifications, quantities, contract type, specifications/		

		templates, period of performance		
Tendering	Procurement Dept.	Tender policy, completed tender documents, supplier specifications		
Bid Evaluation	Program officers, Procurement Dept.	Bid unit prices, historical or known standard international unit prices, supplier service evaluations, pre-qualification		
Contract Management	Procurement Dept. (contracts officer?)	Contract numbers, performance indicators, periods of performance, payment schedules, payment authorizations		
Supplier Management	Procurement Dept. (contracts officer?)	Contract numbers, performance indicators,		UNICEF Copenhagen DB, Clinton Foundation New Delhi DB
Pipeline Monitoring	Program officers, Procurement Dept.	Product list, supplier list, stock on hand, consumption, losses and adjustments, current orders, min/max levels	<i>PipeLine</i>	
Customs Documentation	Procurement Dept., Customs clearance agent	Customs clearance policy, bills of lading, commercial invoices, packing lists, bills of entry		
Invoice Management	Accounts Dept.	Invoice/PO numbers, approvals policy	<i>ACCPAC</i>	
Accounts Payable	Accounts Dept.	Supplier list, invoice/PO numbers, PO values	<i>ACCPAC</i>	
Monitoring Forecast Accuracy	Program officers, Procurement Dept.	Historical forecasts and corresponding consumption records, quantities procured		

WAREHOUSING/INVENTORY MANAGEMENT-RELATED

Inventory Counting	Supply clerk	Stock locations, stock on hand	Stock cards	
Stock Status Monitoring	RMS director, regional logistics officer	Stock on hand, consumption, product shelf-life, losses and	Stock cards, <i>LMIS-01</i> , <i>Supply Chain</i>	

		adjustments	<i>Manager, ACCPAC</i>	
Enforcing FEFO	Chief pharmacist, supply clerk	Stock on hand, Stock locations, expiry dates, lot numbers		
Invoice Management	Accounts Dept.	Invoice/PO numbers, Approvals Policy	<i>ACCPAC</i>	
Issuing	Chief pharmacist, supply clerk	Invoice/PO numbers, product list, quantities, stock-on-hand	<i>ACCPAC</i>	
Picking	Supply clerk	Product list, quantities, stock locations		
Packing	Supply clerk	Invoice/PO numbers, packing list		
Shipping Documentation/Release	Chief pharmacist, Accounts Dept.	Invoice/PO numbers, packing list, product list, quantities, customer information	Delivery notes, commercial invoices, <i>ACCPAC</i>	
Receiving	Supply clerk, chief pharmacist, Accounts Dept.	Invoice/PO numbers, product list, quantities		
Location Management	Supply clerk, chief pharmacist	Physical volume and velocity by product, location plan, location/bay/ slot numbers		
Put-Away	Supply clerk, chief pharmacist	Location plan, location/bay/ slot numbers		
Facility Maintenance	RMS director, supply clerk	Maintenance checklists, maintenance schedules, performance indicators		
Temperature Monitoring	Supply clerk, chief pharmacist	Temperature, date, time		
Monitoring Perfect Order Fill	RMS director	Product list, order quantities, Issue quantities, confirmed delivery quantities	<i>LMIS-01, delivery notes, Supply Chain Manager</i>	

DISTRIBUTION

Route Planning		Customer locations, distances, road conditions, travel time, vehicle requirements	No electronic system used, although <i>Supply Chain Manager</i> has this capability	
Vehicle Scheduling		Order volumes, vehicle	No	

		volumes, customer locations, vehicle requirements	electronic system used, although <i>Supply Chain Manager</i> has this capability	
Loading		Personnel start time, finish time		
Vehicle Use Monitoring		Odometer readings, locations, and known distances		
Driver Performance Monitoring		Driver performance metrics		
Shipping Documentation		Products, quantity shipped, quantity received	Delivery notes, stock cards, ACCPAC	Delivery note
Delivery/Unloading		Personnel, time of arrival on customer site, time of departure from customer site	Delivery note	Delivery note
Vehicle Maintenance		Maintenance schedule, problems		
Monitoring On-Time Delivery		Customer locations, agreed or planned delivery time, departure time, arrival time		

For more information, please visit www.deliver.jsi.com.

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