USAID | DELIVER PROJECT

BUILDING BLOCKS FOR LOGISTICS SYSTEM DESIGN FOR HIV TESTS AND ARV DRUGS

INVENTORY CONTROL SYSTEMS, LOGISTICS MANAGEMENT INFORMATION SYSTEMS, AND STORAGE AND DISTRIBUTION

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Abstract
A logistics system that manages any health commodity must have the infrastructure to support the supply chain as a whole in order to manage and move commodities. This document focuses on four elements that require careful management in the context of HIV and AIDS supply chains: (1) the inventory control system, (2) the logistics management information system, (3) storage, and (4) distribution. It is designed to help logisticians design logistics systems that are appropriate for managing these commodities.

Cover photo: Demonstration of a stockcard.

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ACRONYMS

AIDS	acquired immunodeficiency syndrome
ART	antiretroviral therapy
ARV	antiretroviral
CMS	central medical store
FEFO	first-to-expire, first-out
FPLM	Family Planning Logistics Management
HIV	human immunodeficiency virus
HMIS	health management information system
INN	International Nonproprietary Name
JSI	John Snow, Inc.
LMIS	logistics management information system
NGO	nongovernmental organization
NRL	National Reference Laboratory
PMTCT	preventing mother-to-child transmission
SDP	service delivery point
STG	standard treatment guideline
VCT	voluntary counseling and testing
WHO	World Health Organization
UNAIDS	Joint United Nations Programme on HIV & AIDS
UNFPA	United Nations Population Fund
UNICEF	United Nations International Children's Emergency Fund
USAID	U.S. Agency for International Development

ACKNOWLEDGMENTS

This publication, which is featured on the CD *Resources for Managing the HIV & AIDS and Laboratory Supply Chains*, is dedicated to people around the world living with HIV and acquired immunodeficiency syndrome (AIDS) and to the many individuals from communities, nongovernmental organizations (NGOs), faith-based organizations, Ministries of Health, and other organizations who have consistently fought for access to antiretroviral drugs and other commodities required to provide HIV and AIDS services. The publication is also dedicated to friends and counterparts who have worked with the USAID | DELIVER PROJECT, the Family Planning Logistics Management project, and John Snow, Inc., since 1986 and to the thousands of committed professionals in Ministries of Health and NGOs who work daily to supply their customers and programs with essential public health commodities. Although the resources on the CD provide a focus on specific HIV and AIDS and laboratory commodities, we recognize that comprehensive HIV and AIDS and laboratory programs require the supply chain to manage and deliver a broad range of several hundred public health commodities.

U.S. Agency for International Development (USAID) contracts funded the technical assistance, in-country projects, and research that produced the experience and lessons contained in the *Resources*. We are deeply grateful to the team of professionals in the Commodity Security and Logistics Division in the Office of Population and Reproductive Health of the USAID Global Health Bureau's Center for Population, Health, and Nutrition for their encouragement and advice and their commitment to improving HIV and AIDS laboratory and public health programs through logistics.

Numerous people helped write the documents that constitute the *Resources*. Sincere thanks go to the core team of dedicated technical staff who developed and wrote the components both in the field offices and in Washington, DC. The lessons drawn from the USAID | DELIVER PROJECT's experience in managing HIV and AIDS and laboratory supply chains would not have been possible without these valuable contributions.

EXECUTIVE SUMMARY

INTRODUCTION

The public health landscape is changing rapidly throughout the world. The infusion of resources from major initiatives to combat devastating health problems, such as HIV and AIDS, have provided many benefits but have also increased the complexity of and the burden on public health supply chains. Countries are being asked to manage an increasing number and volume of products, and these growing demands can put tremendous strain on public health supply chains. As a result, it will be increasingly important for countries to take a holistic view of public health systems and optimize their supply chains in order to most efficiently and effectively use scarce resources and to ensure commodity security for all health commodities.

Some countries have chosen to develop vertical supply chains for ARVs or HIV tests, while others have chosen to integrate all or some portion of the logistics systems for these commodities. The decisions on what functions to integrate, as well as how and when to integrate them, need to be examined carefully. Regardless of whether antiretrovirals (ARVs) and HIV tests are vertical, or partially or fully integrated with other health commodities, this document outlines recommendations for system design for the management of these commodities.

A logistics system that manages any health commodity must have the infrastructure to support the supply chain as a whole in order to manage and move commodities. This document focuses on four elements that require careful management in the context of HIV and AIDS supply chains: (1) the inventory control system, (2) the logistics management information system, (3) storage, and (4) distribution. It is designed to help logisticians design logistics systems that are appropriate for managing these commodities.

When providers do not have consistent supplies of ARVs because of nonfunctioning or poorly functioning supply chains, treatment can be severely compromised. Providers may even prescribe ARV drugs in combinations that can be toxic, lethal, or ineffective for antiretroviral therapy (ART). In one country, patients were being treated with the six following combinations of drugs, *none* of which were included in the local standard treatment guidelines (STGs) or in STGs recommended by the World Health Organization (WHO):

- ABC/AZT/3TC
- ZT/ddI/NVP
- d4T/3TC/IDV
- d4T/3TC/NLF
- d4T/ddI/
- 3TC/AZT/IND

CHARACTERISTICS OF ARV DRUGS AND HIV TESTS

ARV drugs and HIV tests have particular characteristics that influence how they are managed. Compared to many other essential medicines, ARVs and HIV tests may require special handling or adjustments to the supply chain through which they are managed. The special nature of ARVs and HIV tests will influence the design of the inventory control and logistics management information systems and the storage and distribution networks.

Characteristics of ARV drugs and HIV tests include—

- High value in prolonging survival for HIV positive patients
- Need for continued, uninterrupted resupply for patients already on ART
- Dynamic technology for products leading to evolving treatment and testing protocols
- Treatment and testing protocols that require multiple products to be available simultaneously to provide a service
- Higher levels of accountability, including special reporting or other documentation requirements from either donors or manufacturers
- Limited number of sites authorized to use ARV drugs
- For ARVs, high risk in the case of stockouts, given—
  - Limited possibility for product substitution
  - Limited availability outside of public sector facilities.
- Relatively short shelf life that can range from six to 36 months
- For ARVs, significantly high prices relative to most essential medicines
- Cool or cold storage required for some products
- For HIV tests, other commodities needed to administer the test

RECOMMENDATIONS

The following recommendations are guiding principles and lessons learned from the USAID | DELIVER PROJECT's experience that have proven effective in supply chain management of ARVs and HIV tests.

Inventory Control System

- Ensure that the length of the supply pipeline accommodates the shelf life of products.
- The forced ordering version of the maximum-minimum (max-min) inventory control system has proven most effective in ensuring product availability.
- If demand is unpredictable, such as for a rapidly expanding program, consider any of the following:
  - Increase the amount of buffer stock so that inventory is on hand to respond to increases in demand.
  - Reduce lead times to be able to move product quickly through the supply chain.
  - Invest in improving forecast accuracy to better predict demand.
- Implement a routine reporting period and order cycle based on key system parameters.
- For ARVs, implement standardized dispensing protocols to enhance logistics data credibility, analyze consumption trends, and manage stock levels appropriately.

Logistics Management Information System

- Link routine reporting to commodity resupply.
- Always collect and report dispensed-to-user data for ARVs and usage data for HIV tests; do not use issues data as a proxy.
- Collect and report the total number of days products were out of stock in the reporting period.
- Avoid overburdening the logistics management information system (LMIS) by collecting service statistics or other data that are not used for supply chain decision making.
- For ARVs, use the International Nonproprietary Name (INN) on all LMIS forms.
- For all LMIS forms, leave blank spaces for new drugs or products to be added.
- In addition to the three essential logistics data items—
  - For ARVs, collect and report the number of existing patients by treatment regimen.
  - For HIV tests, collect and report consumption of tests by purpose of testing.
- Calculate order quantities using consumption data.
- Select and consistently use the same unit of measure when reporting products.
- For HIV tests, determine how the additional consumables required for testing will be resupplied to the testing facility.

Storage and Distribution

- Provide for appropriate security during storage and distribution.
- Adhere to first-to-expire, first-out (FEFO) procedures.
- Ensure product integrity if reissuing returned products.
- Consider outsourcing storage and distribution as a way of strategically managing resources.

INTRODUCTION

The public health landscape is changing rapidly throughout the world. The infusion of resources from major initiatives to combat devastating health problems, such as HIV and AIDS, have provided many benefits but also have increased the complexity of and the burden on public health supply chains. Countries are being asked to manage an increasing number and volume of products and these growing demands are putting tremendous strain on public health supply chains. As a result, it will be increasingly important for countries to take a holistic view of public health systems and optimize their supply chains in order to use scarce resources most efficiently and effectively and to ensure commodity security for all health commodities.

Some countries have chosen to develop vertical supply chains for ARVs or HIV tests, while others have chosen to integrate all or some portion of the logistics systems for these commodities. The decisions on what functions to integrate, as well as how and when to integrate them, need to be examined carefully. Regardless of whether ARVs and HIV tests are vertical, or partially or fully integrated with other health commodities, this document outlines recommendations for system design for the management of these commodities.

A logistics system that manages any health commodity, ARVs, HIV tests, or otherwise, must have established infrastructure which supports the supply chain as a whole in order to move and manage commodities. This infrastructure includes—

- A commodity resupply pipeline
- An information system for gathering and using commodity data
- Storage facilities, including cool storage facilities
- A distribution system (pickup or delivery), based on the availability of reliable transportation
- Staff/human resources to implement the system

Inventory management is a vitally important function of every logistics system, as it determines how stock is managed during ordering, stockkeeping, distribution, and resupply. Inventory management comprises the procedures that govern how these commodities are ordered, received, stored, handled, and distributed to other facilities or dispensed to users at service delivery points (SDPs). The purpose of inventory management is to ensure a continuous supply of quality products to users whenever and wherever they are needed.

This paper focuses on four elements of supply chain and pipeline management: the inventory control system, the logistics management information system, storage, and distribution. These elements require careful management in the context of ARV drugs and HIV tests. This paper is intended to help logisticians design logistics systems that are appropriate for managing these commodities.

Continuous Improvement

All logistics systems should be managed through the lens of continuous improvement. The environment in which logistics systems operate is dynamic, as new products are added, health policies are amended, and the systems themselves mature and evolve. Because of this changing landscape, it is important that logisticians and supply chain managers recognize that systems will need to adapt to new environments and circumstances.

After designing a logistics system, supply chain managers will need to monitor lead times, stockout frequency, reporting levels, supervision, and other factors to understand how well the system is functioning. In some cases, improvements can be made immediately, such as adding transport resources, providing additional on-the-job training, or increasing supervision. System designers will always find ways to improve the system. Some solutions will be easy, while some will be more extensive, but the goal is to discover ways to ultimately serve the client, patient, or customer better—to ensure product availability whenever and wherever customers need them. Managers should use all sources of information (reports, word of mouth, and others) to continually improve the system.

Securing a dependable, regular supply of ARV drugs or HIV tests at SDPs is critical to the success of ART programs and laboratory diagnosis. Any interruption in the supply chain will prevent diagnosis of new patients or endanger the lives of patients already on therapy because of the risk of discontinuation of treatment or development of drug resistance. Frequent interruptions will compromise the success of the program.

Refer to *The Logistics Handbook* (John Snow, Inc., 2004i) for basic guidance on supply chain design and implementation.

INVENTORY CONTROL SYSTEMS

PURPOSE OF AN INVENTORY CONTROL SYSTEM

An inventory control system informs the storekeeper—

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

The continuous supply of quality ARV drugs and HIV tests can be guaranteed only through the selection, design, and proper implementation of an appropriate inventory control system. A number of strategies or inventory control systems can be designed or adopted to manage commodities of any kind. Some of these, such as a rationing system, are more appropriate in situations where there is uncertainty or shortages in the product supply being managed or the financial resources available to purchase the products being managed. In a traditional rationing system, supplies are allocated on the basis of some set of chosen criteria—for instance, to serve a certain proportion of the poorest clients, to treat a certain proportion of the priority disease burden in the region, or to ensure that a certain product accounts for no more than a certain proportion of the available budget. However, ARV drugs and HIV tests are expected to be in full supply for a desired number of patients, at least in the short term. To manage full-supply products appropriately, a maximum-minimum inventory control system (also known as a max-min system) is recommended and has been shown to work effectively.

MAXIMUM-MINIMUM INVENTORY CONTROL SYSTEMS

Full-Supply Situation

Implementation of a max-min inventory control system is most effective in a full-supply situation, where sufficient quantities of all commodities are available to meet all needs, as should be the case for an ART program and some programs that use HIV tests (e.g., voluntary counseling and testing [VCT], provider-initiated counseling and testing [PITC], or preventing mother-to-child transmission [PMTCT]).

A max-min system allows objective resupply decisions based on need and takes into account established levels of safety stock, with the ultimate goal of having product available each and every time it is needed. Given the life-saving nature of ART and the public health risks associated with the emergence of ARV drug resistance, uninterrupted product availability must be the primary concern.

When designing a logistics system, one of the first decisions that will have to be made is the type of max-min inventory control system to use. There are several types of max-min inventory

control systems, each of which has slightly different transportation, personnel training, and storage requirements and the other elements that comprise a supply pipeline. Among the options are—

Forced ordering: Orders are placed at regular intervals; all products are ordered/resupplied to the maximum stock level.

Delivery truck variation of forced ordering: Rather than submitting orders to the supplying facility, SDPs are visited regularly (the length of the reporting period) by a resupply truck. At the time of the visit, data are collected and resupply quantities are determined and delivered.

Continuous review: Orders are placed each time a product reaches its minimum stock level; products reaching the minimum stock level are ordered and resupplied to the maximum stock level.

Two-bin variation of continuous review: Bin sizes are determined by the system designers so that one bin equals the estimated consumption for one reporting period. When the contents of one bin have been distributed (i.e., at the end of the reporting period), a new bin is resupplied to the dispensing facility.

Standard: Orders are placed at regular intervals, but a product is ordered only if it has reached its minimum stock level; products reaching the minimum stock level are ordered and resupplied to the maximum stock level.

Refer to *The Logistics Handbook* (John Snow, Inc., 2004) for a more complete description and additional discussion of the various max-min systems.

Pull or Push System

In any version of the max-min system, the designer must also decide where the decision-making power lies for determining reorder quantities: "pull" if personnel receiving the supplies make the decision, "push" if personnel issuing the supplies make the decision.

The choice of implementing a push or a pull system will depend largely on in-country capacity at each level of the supply chain as well as the availability of technology. Countries/programs that have well-trained staff at the lower levels (or the potential to train such staff adequately) could easily choose a pull system. Countries/programs that rely on more trained staff or the availability of computerized systems at the upper levels, or those wishing to reduce the commodity management workload of lower-level staff, could choose a push system. In either case, adequate information and data have to be available; see the Logistics Management Information Systems section for further discussion of this topic.

> Note: Do not confuse "push system" with "rationing." Although push systems have historically been used when commodities are rationed, not all push systems are rationing systems. A true push system can be equally, if not more, effective than a pull system if data are accurate and routinely available.

Length of In-Country Commodity Pipeline

The length of the commodity pipeline (determined by adding the maximum stock levels at all levels of the system) is a key consideration in commodity management. This is especially true for ARVs and HIV tests, where a commodity's shelf life is often less than 36 months and can be as short as six months.

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

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

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

Max = minimum + review period

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

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

The more effective and efficient the elements of the supply chain (transportation system, order turnaround time, etc.), the more effective and efficient the supply chain, and therefore, the shorter the pipeline can be. In a system for managing ARVs and HIV tests, supply chain effectiveness and efficiency must remain a top priority.

CHARACTERISTICS OF ARV DRUGS AND HIV TESTS THAT AFFECT THE SELECTION/DESIGN OF AN INVENTORY CONTROL SYSTEM

ARV drugs and HIV tests have characteristics that may require that they be managed differently (with greater control, with greater care, using a different system) than other commodities. Managing them may require establishment of a vertical supply chain or special handling within an integrated or other combined supply chain. Characteristics of ARV drugs and HIV tests include the following:

- High value in prolonging survival for AIDS patients
- Need for continued, uninterrupted resupply for patients already on ART
- Dynamic technology for products leading to evolving treatment and testing protocols
- Treatment and testing protocols that require multiple products to be available simultaneously to provide a service
- Higher levels of accountability, including special reporting or other documentation requirements from either donors or manufacturers
- Limited number of sites authorized to manage ARV drugs

- For ARVs, high risk in the case of stockouts given—
  - Limited possibility for product substitution
  - Limited availability outside of public sector facilities.
- Relatively short shelf life that can range from six to 36 months
- For ARVs, significantly high prices, relative to most essential medicines
- Cool or cold storage required for some products
- For HIV tests, other commodities needed to administer the test

Because of these unique characteristics, it may not be possible to integrate ARV drugs and HIV tests fully into existing inventory control systems. For instance, holding large quantities of stock in inventory at the various levels requires more money and storage space and increases the risk of pilferage, damage, and expiration.

In view of the logistics system design elements and the key considerations already discussed, the USAID | DELIVER PROJECT has developed some basic recommendations for designing and implementing an inventory control system to manage ARV drugs and HIV tests.

RECOMMENDATIONS FOR ARV DRUG AND HIV TEST INVENTORY CONTROL SYSTEM DESIGN AND IMPLEMENTATION

The following recommendations will achieve pipeline efficiency while addressing the special commodity management requirements of ARV drugs and HIV tests.

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

The length of the supply pipeline must accommodate the relatively short shelf lives of ARV drugs and HIV tests, which average between six and 36 months. From the pipeline described in the table above, it is clear that a pipeline of 29 months is too long to manage ARVs and HIV tests, many of which are delivered in-country with about 75 percent of their shelf life remaining. Each level in the pipeline necessarily implies safety stock kept at each level, with the potential of tying up valuable financial resources in stock quantities.

System designers may need to reduce the length of the in-country supply pipeline to accommodate these products. Strategies for minimizing the length of the supply pipeline are listed below. It must be noted that any of these strategies must be selected based on the in-country situation and resources. Adopting a strategy that affects one element of the supply chain will have an impact on other system elements, and the operation of the supply chain will be adversely affected if any one element is not strong enough to perform under the new requirement.

- **For managing commodities, utilize as few levels as possible in the supply chain.** This is the single most effective and most common strategy for ensuring relatively shorter in-country pipelines. In many countries, intermediate levels such as regional and/or district levels have been eliminated, and commodities move directly from the central level to the SDPs. In the table above, eliminating the district level alone would reduce the overall pipeline to 23 months;

removing the regional level alone would reduce the overall pipeline to 21 months; and removing both the regional and district levels would reduce the overall pipeline to only 15 months. Although this results in storage and distribution savings at these levels, this approach does require more resources for transportation at all levels.

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

- **Shorten the order interval at one or more levels.** Although this will reduce the pipeline length by reducing the maximum stock level, it will require more frequent reporting and ordering, which may place a burden on service providers to report more frequently and require more frequent transportation—for example, monthly pickup/delivery instead of quarterly. Further, care must be taken that **the lead time does not exceed the reporting period** for placing and receiving an order, because if sites do not receive their last order before they place their next order, this will distort the quantity they have on hand and the quantity they order.
- **Reduce the lead time.** Overall pipeline length can be reduced by reducing the amount of time it takes to fill and process orders and deliver product to the receiving facility. Of course, this increases pressure on personnel and transportation resources. Automation of data collection, reporting, analysis, and order processing can also help to reduce lead times. Reducing the lead times will reduce minimum and maximum stock, minimizing the chances of expiries.
- **Maintain lower levels of safety stock.** Safety stock is kept primarily because of uncertainty about the system's ability to provide routine service. If uncertainty can be reduced—for instance, if suppliers consistently provide timely delivery, if customs clearance formalities are reduced or eliminated, or if communications and transportation within the country are very reliable—the safety stock level can be reduced, along with both minimum and maximum stock levels. However, if the program is rapidly expanding or demand is unpredictable, safety stock should not be reduced.

2. The forced ordering version of the max-min inventory control system has proven most effective in ensuring product availability.

For ARVs and HIV tests, many countries, including Ghana, Kenya, Malawi, Nigeria, Uganda, Zambia, and Zimbabwe, have selected the forced ordering max-min system. The forced ordering version of max-min inventory control system has several key benefits:—

- The range/number of commodities is relatively limited/low, so all commodities can be ordered at each reporting period.
- The simple ordering decision rule makes it easier to implement.
- Because all items are ordered at the end of every review period, storekeepers do not need to assess stock status constantly, unless they believe there is potential for a stockout to occur.

- If ordering is linked to reporting, forced ordering will require that all facilities submit a report/order at each order interval, so facilities that are not reporting and/or not ordering can be identified easily.
- Because facilities do not have to wait to reach the minimum stock level before ordering, less buffer stock is required than in the standard system.
- Because orders are placed at regular intervals (i.e., the end of each review period), transportation can be scheduled for specific times, making it easier to ensure the availability of transport resources. (This system entails less frequent orders and deliveries than does a continuous review system.)

Depending on the number of ART and HIV testing sites being served, the reliability of transportation, the size of the country, and other factors, the delivery truck variation of forced ordering max-min can be a good choice for ARV drug and HIV test distribution. ARVs and HIV tests **must** be in **full supply** for this system to be considered. The delivery truck variation of forced ordering max-min does put pressure on distribution planning and transport management, but it has benefits in addition to those of the forced ordering system noted above:

- Higher level of security: supplier vehicles can be upgraded to ensure secure cargo areas rather than retrofitting service facility vehicles for the task.
- Immediate data collection: data are collected at the moment the vehicle arrives at site; there is no delay due to data transmission, so resupply decisions are based on very timely data; and there is less risk of the data/information being lost in transmission.
- Lead time is negligible, thus shortening the pipeline.
- Relieves service providers of some logistics duties: data collection, resupply, etc., are done by the delivery team. Routine stock management is still the responsibility of facility staff.
- Centralizes transport needs: dedicated vehicles ensure supply deliveries so individual sites do not need to arrange for transportation of commodities.
- Excess product close to expiry can be collected for immediate redistribution to other sites; expired product can be collected for disposal.
- If a supervisor accompanies the delivery, on-the-job training and some supervisory activities can take place at the time of the delivery.
- In case some elements of the system need to be adapted, only a small number of staff (delivery teams) need to be trained, rather than staff from every SDP in the country.

3. If demand is unpredictable, such as for a rapidly expanding program, consider any of the following:

- **Increase the amount of buffer stock so that inventory is on hand to respond to increases in demand.**
  Increasing the amount of buffer stock at the site level will enable facility staff to respond directly to increases in consumption, without facing imminent stockouts. It will also make emergency orders less likely, since stock will be immediately on hand. Buffer stock could also be increased

at the higher level, so that the issuing facility has commodities on hand so that it can respond with resupply.

- **Reduce lead times to be able to move product quickly through the supply chain.** Reducing the time that it takes to review and process orders will enable the product to move more quickly from the higher level to the lower level. This speed is of heightened importance in the case of emergency orders, where responsiveness is critical.
- **Invest in improving forecast accuracy in order to better predict demand.** Accurate forecasting is an important factor in ensuring that appropriate quantities of product are procured and available in country. In a rapidly expanding program without established historical data, it can be difficult for logisticians to estimate the rate at which the program will scale up. Investing in more accurately estimating the quantities of products expected to be consumed can result in improved product availability. Forecast accuracy can be improved by training staff in forecasting methodologies and tools and in data collection and reporting, and by comparing forecast consumption data with actual consumption data on a regular basis and adjusting the forecast as needed.

4. Implement a routine reporting period and order cycle.

During the initial expansion of HIV treatment and testing programs, many countries chose to implement a monthly reporting period and order cycle. One reason this was done was to limit the amount of buffer or safety stock that facilities need to hold. Further, monthly ordering and reporting allowed program managers to monitor the quantities and range of products being used more frequently to respond to changes in product requirements and adjust procurements. However, as HIV treatment and testing programs have matured, for many countries implementing a bimonthly or even quarterly reporting and ordering period is more sensible. Having a longer reporting period means that the central level does not have to review reports and process orders for every facility in the country every month. A longer report period also relieves the reporting burden on the facility-level staff, who have to report less frequently. It can allow central-level staff more time to provide support and supervision to facility staff and to follow up with nonreporting facilities.

When determining the appropriate reporting period and order cycle, it is important to ensure that the lead time is always less than the reporting period.

Designers can also consider staggering the dates that reports and orders are due across the country. For example, if a country has four regions and has selected a bimonthly reporting period, two of the regions can report at the end of odd months (January, March, May, July, September, and November) and the other two regions can report at the end of even months (February, April, June, August, October, December). This setup can help central-level staff and supervisors manage a demanding workload. System designers must consider the in-country situation and geography when determining whether staggered reporting is feasible.

5. For ARVs, implement standardized dispensing protocols to enhance logistics data credibility, analyze consumption trends, and manage stock levels appropriately.

Standardized dispensing protocols refer to the quantity of ARV drugs given to patients when they are resupplied by the facility. Most commonly, patients are given between one and three months of supply. When the same quantity of ARV drugs is given to patients every time they are resupplied, the consumption data collected can be compared to and used to validate the patient data collected. Having standardized dispensing protocols allows for a reliable calculation of average monthly consumption. Standardized dispensing protocols also allow for analysis of consumption trends, as they make consumption levels more predictable from month to month, which is important for resupply decisions and for forecasting. To manage stock levels appropriately, the same quantity of drugs should be given to patients every time they are resupplied. If dispensing protocols vary widely in a country, it is difficult for a facility to manage its stock levels appropriately, as intended in the system design. For example, if one month a facility gives patients four months of supply, and the next month the same facility gives one month of supply, this will skew the consumption trends. It also makes it impossible to compare consumption data with patient data for the purposes of validating order quantities and forecasting and predicting future consumption patterns. System designers should consider dispensing protocols when setting the review period.

LOGISTICS MANAGEMENT INFORMATION SYSTEMS

PURPOSE OF A LOGISTICS MANAGEMENT INFORMATION SYSTEM

In all programs and for all product categories, logistics managers at all levels need to make routine decisions that affect commodity availability. They need to determine how much of each product to order or resupply, to forecast future demand for a product, and to plan procurements and commodity shipments. They also need to be able to identify potential supply problems at facilities or storage sites or to handle other issues related to commodity management. These decisions must be made using accurate and timely logistics data that are provided by a logistics management information system (LMIS). Over the long term, data provided through the LMIS can also help inform policy and product selection decisions.

> Do not confuse an LMIS with a health management information system (HMIS). HMISs are intended for collecting and reporting overall program parameters, such as incidence, client load, and performance, and lack the specificity that LMISs provide for managing commodities within the health program. In addition, the time required to collect and process data through an HMIS would mean that they are not available for timely logistics decision making.

An LMIS helps personnel collect and manage the information necessary to support sound and objective decision making in managing the supply chain; the goal of this decision making is to ensure an uninterrupted supply of commodities and to identify any problems in the supply pipeline. The LMIS is composed of all the forms and documentation used to maintain records and produce reports on the logistics system.

An effective LMIS makes regular and timely information available to decision makers. Information is used to make short-term resupply decisions and long-term procurement and program management decisions. Timely and accurate commodity data are critical for logistics system performance.

LINK BETWEEN THE LOGISTICS MANAGEMENT INFORMATION SYSTEM AND THE INVENTORY CONTROL SYSTEM

An LMIS and the inventory control system have a close relationship: the LMIS provides the data required to maintain the inventory control system.

Data collected through the LMIS enable a product manager to determine how many months of stock are currently kept at the facility; knowing this, the product manager will know if the supply is above, below, or within the established maximum and minimum stock levels, or whether an emergency order must be placed. At the end of the order interval, the product manager will

compare current stocks to maximum stock level and order the quantity needed to bring stock levels to maximum.

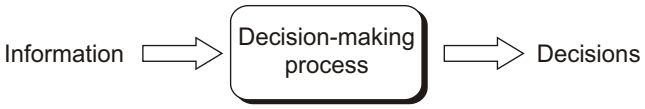
Upper-level commodity managers can use the LMIS to track trends in overall consumption and adjust national-level procurements as needed. They can identify overstocks of ARVs or HIV tests and redistribute the products. Commodity managers can also use the data to identify exceptionally high levels of product expiry, and then initiate action to prevent this situation from recurring.

LMIS data can even help program managers identify incorrect prescribing or dispensing practices or detect unusually high rates of treatment failure at a particular site or in a region. This can result in targeted supervision and, thus, improve the overall quality of care for HIV and AIDS clients.

DATA FOR DECISION MAKING

A key underlying principle for all LMISs is that data collected and organized will provide a sound basis for decision making. This requires that relevant data be collected at appropriate locations in the logistics system, processed, and transmitted to decision-making points in a timely and complete manner. Additionally, decisions must be based on reliable data, so care must be taken to ensure data integrity, to avoid duplication, and to collect only the data that are actively used for decision making.

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



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

Dispensed to user/usage: The quantities of products given to clients/patients for their use (e.g., ARVs) or the quantities of products used by the service provider (e.g., HIV tests, which are not actually given to the clients)

Stock on hand: The usable quantities of stock held at a facility

Losses and adjustments: Any quantity of stock that leaves the pipeline for reasons other than dispensed to user—transfers of stock from one facility to another at the same level, expiry, or damage

While using issues data as a proxy for dispensed-to-user data may be acceptable in general essential medicines programs, the level of rigor and accountability required of HIV and AIDS programs makes this practice unacceptable for managing ARV drugs and HIV tests. In addition, concerns for the security of ARVs from therapeutic, safety, and financial perspectives impose greater demands for accountability.

Other data may be included in an LMIS; however, an LMIS must not try to collect data not relevant for logistics management decision making, since it will become a burden on the health care personnel who implement the system. Burdening an LMIS with such additional data risks slowing it down, preventing data from being transmitted in a timely way to make decisions. An LMIS must collect only data that will be used for supply chain decision making. The forms and reports used to collect and transmit the data must also be easy to use.

The logistics data that are collected and reported will be used to answer a number of questions, including the following:

- How long will available supplies last; do we need to order more supplies now?
- Where are our supplies in the pipeline; do we need to move supplies from higher to lower levels or between facilities at the same level?
- Where is consumption the highest? Do those facilities need more resources?
- Are we experiencing losses from the system that require us to take action?
- Are supplies flowing regularly through the pipeline? Do we need to adjust the pipeline to eliminate bottlenecks in the system?

RECORDS AND REPORTS

As mentioned earlier, the purpose of a logistics system is to collect and process data to support decision making. Three kinds of logistics records, which correspond to the three essential data items, are typically used to collect data at the points at which the commodities are managed:

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

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

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

In addition to the reports that move up the system, feedback reports are often used to provide information from the higher to the lower levels of the system. In this way, lower-level facilities can gain an appreciation of how the work they do fits within the overall system and see how lower-level operations can be improved. Feedback reports also give the facilities information about what they could be doing better (i.e., in filling out their forms) and shows them that the information that they are submitting is being used and disseminated throughout the system.

AVAILABILITY OF DISAGGREGATED DATA

Assuming that ARV drug or HIV test pipelines are shorter than the pipelines used for moving other kinds of commodities, as was recommended earlier, the amount of data aggregation may be reduced. For example, a country may have started with a three-level system (SDP, district, central) in which the district aggregates data from the sites and adds district-level data. These aggregated reports are sent to the central level, which then aggregates the information from the districts. If the system designer decides to eliminate the district level, SDPs will send reports directly to the central level, where the data will be aggregated. This will reduce the risk of introducing errors into the reporting system and will help to ensure that data continue to move regularly and rapidly through the system.

As data move from the lower levels to the upper levels, some data elements may be aggregated. For instance, a team of service providers at a facility may submit a total figure at the end of the month that shows the number of drugs dispensed. In this case, the facility would report only the total number, not the number of drugs dispensed by each individual service provider.

As the data move higher through the system, however, care must be taken to ensure that upper-level decision makers have access to disaggregated data, which they need for their decision making. For instance, it might be useful for ART or HIV testing program managers to know the total of all products and/or regimens dispensed in all sites/facilities, or the total quantity of products held at all sites/facilities. But for the purposes of supervising the logistics system and overseeing distribution of products among the districts, the program managers would need to have the data disaggregated by SDP.

Refer to *The Logistics Handbook* (John Snow, Inc., 2004i) for a more complete description and additional discussion of logistics management information systems.

CHARACTERISTICS OF ARV DRUGS AND HIV TESTS THAT AFFECT THE DESIGN AND IMPLEMENTATION OF A LOGISTICS MANAGEMENT INFORMATION SYSTEM

While an uninterrupted supply of commodities is desirable for all health programs, ARV drugs and HIV tests present unique challenges. Unlike some other medicines, one ARV cannot easily be substituted for another. In addition, the requirement that different ARVs be used in specific combinations necessitates that these products be monitored both separately and in combination. Furthermore, ART cannot be interrupted and continued later because of the unavailability of drugs. Any failure in the supply chain to make ARVs and related supplies available at all times could lead to catastrophic outcomes, including treatment failure, development of drug resistance, and death. As with ARV drugs, there are no substitutes for HIV tests after specific testing protocols have been established for each test purpose; chase buffer from one test kit, for example, cannot be used with a different kit. An HIV test protocol may require the use of up to three different tests, all of which must be available to give clients reliable test results.

Issues of particular concern in ARV drug and HIV test management, all requiring accurate and timely information:

- Need for continued, uninterrupted resupply for patients already on ART
- Treatment and testing protocols that require multiple products to be available simultaneously
- Higher levels of accountability, including special reporting or other documentation requirements from either donors or manufacturers
- For ARVs, high risk in the case of stockouts, given—
  - Limited possibility for product substitution
  - Limited availability outside of public sector facilities
- Relatively short shelf life that can range from six to 36 months
- For HIV tests, other commodities needed to administer the test

As with the inventory control system, it may not be possible to fully integrate the LMIS used to manage ARV drugs and HIV tests with the LMIS used to manage other health commodities. Certainly, a vertical system for managing ARVs or HIV tests would require its own vertical LMIS.

At the program management level, for program planning, quantification, and procurement planning, additional, nonessential logistics information often may be needed for effective decision making. This additional information cannot be compiled from logistics data, but must come from patient and program data that should be collected routinely through the HMIS established for the HIV and AIDS program. Ideally, logistics managers should have access to information available through the HMIS to facilitate program planning and routine supervision. System designers must note that even if the HMIS functions well, the kind of data required for supply chain decision making may not be available in a timely manner. In the absence of a well-functioning HMIS, some (but not all) of these data elements should be collected through the LMIS.

Following is a sample list of the types of additional information useful to logistics managers for program planning. Some of the information comes from primary data and some is calculated from primary data.

Additional information useful for ART program management:

- Number of patients who access ART services and receive drugs
- ARV combinations and regimens
- Changes in overall use of regimens over time (calculated data)
- Rates of patients substituting single drugs due to toxicity (calculated data)
- Rates of patients switching regimens (calculated data)
- Changes in pediatric regimen due to weight gain, intolerance, toxicity, or treatment failure
- Weight bands of pediatric patients
- Number of sites that dispense ARVs
- Number of patients on each regimen at each facility
- Correlation between the number of patients and the quantities of drugs being consumed

Additional information useful for HIV testing program management:

- Number of clients/patients who access VCT , PMTCT, or PITC services and are tested
- Number of tests used, by purposes of use, brand, and use of test
- Test-related supplies required for test administration

RECOMMENDATIONS FOR ARV DRUG AND HIV TEST LOGISTICS MANAGEMENT INFORMATION SYSTEM DESIGN AND IMPLEMENTATION

1. Link routine reporting to commodity resupply.

There are many benefits to linking routine reports to commodity resupply. For example, a system with monthly reporting and monthly ordering/resupply has inherent advantages over a system with monthly reporting and quarterly ordering/resupply. Often, commodity managers may ignore reporting that does not produce a tangible benefit or result, which in this case involves receiving commodities that result from an order linked to a report. The following are other advantages to linking reporting and resupply:

- Supervisors can verify more easily that order quantities are realistic, using the data that are reported (consumption, stock on hand, number of patients by treatment regimen).
- Commodity managers will not focus on orders to the exclusion of reports.
- The relationship between the data in the reports and the commodity orders is reinforced; reported data are used for decision making.

Although some might argue that "no report, no commodities" would penalize nonreporting facilities, it is crucial to remember that the data in the reports drive the entire system and ensure adequate commodity orders and procurement for the entire country. Facilities that do not submit their reports regularly and on time jeopardize commodity availability and the system as a whole and, therefore, quality of care. Given the public health risks associated with treatment interruption of ART, linking ordering and reporting has proved to be an acceptable solution. However, policymakers or relevant authorities should always be involved in approving this decision. The "no report, no commodities" method has proved successful in increasing the reporting rate in a number of countries where there was strong political support for this approach.

See the forms in Appendix B, *LMIS Report and Request for Antiretroviral Drugs and LMIS Report and Request for HIV Tests.*

2. Always collect and report dispensed-to-user data for ARVs and usage for HIV tests; issues should not be used as a proxy.

While the use of issues data as a proxy for dispensed-to-user or usage data may be acceptable in general essential medicines programs, the level of rigor and accountability required in ART programs makes this practice unacceptable for ARV drug and HIV test management. In addition, concerns for the security of ARVs and HIV tests from therapeutic, safety, and financial perspectives

impose greater demands for accountability. Dispensed-to-user data reflect what was actually dispensed to patients, and are an essential data item for supply chain management.

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

In a logistics system, stockout data are critical for monitoring the performance of the supply chain and to highlight supply gaps that should be corrected. In ART programs, a stockout of any product can lead to a patient being unable to adhere to treatment, and to overall drug resistance. Collecting and reporting the total number of days each product was out of stock can be used to inform resupply decisions and can help forecast future consumption more accurately. LMIS reports should include a section for the SDP to report the total number of days that each product was out of stock.

4. Avoid overburdening the LMIS by collecting service statistics or other data that are not used for supply chain decision making.

Other data that are not required for logistics purposes may be included in the LMIS for HIV tests or ARVs, depending on the needs of the particular program's existing information systems and logistics system design. The LMIS may be required to capture additional types of data, such as service statistics and epidemiological data, which are often needed by different HIV and AIDS program managers. These types of data can ultimately help in making logistics-related decisions, such as forecasting. Designers should not burden the LMIS by collecting information that is collected in other health information management systems. Logistics system designers should review other reports and records used for capturing and reporting these data to help them decide what data items need to be captured in the LMIS. LMIS reporting formats should not collect any data that are not used for supply chain decision making.

5. For ARVs, use the International Nonproprietary Name (INN) on all LMIS forms.

Since many countries initiated ART, a number of manufacturers of ARV drugs have emerged. In addition to the manufacturer of the originator drug, the number of generic manufacturers has markedly increased. Both originator companies and generic companies have brand names for the ARV drugs they produce. Suppliers of ARV drugs to countries can vary from year to year as prices become more competitive, and donor commitments can change. For LMIS forms to stay constant in this changing environment, the INN for ARV drugs should be used on all records and reports. For example, lamivudine should be used on LMIS forms, rather than Epivir ® (lamivudine manufactured by GlaxoSmithKline) or Lamivir ® (lamivudine manufactured by Cipla).

6. On all LMIS forms, leave blanks for new drugs or products to be added.

As new technology in ARV and HIV testing programs develops, and ART and HIV testing programs grow and mature, standard treatment guidelines and protocols evolve. Whenever a new product or new ARV drug is added to the program, LMIS forms should not have to be changed. To accommodate additions or changes in products used, blank spaces should be included in dispensing and usage registers as well as LMIS reports, so that the user can write in these products if necessary. In the spirit of continuous improvement, the LMIS forms should be revised and reviewed periodically to ensure that they accommodate the products being managed by the logistics system.

7. In addition to the three essential data items, for ARVs, collect and report the number of existing patients by treatment regimen.

To make informed program-wide decisions related to commodity use—forecasting, scale-up of programs, or other medium- or long-term planning—commodity managers, program managers, and others at the higher levels require information on the number of patients/clients by regimen, in addition to the logistics data. Patient data should be used to validate consumption data, to analyze trends in consumption, and to inform resupply decisions. Unlike other public health programs that strive to meet the needs of most if not all potential clients, ART programs usually can treat only a specified number of patients, so these data help managers monitor the numbers of patients under treatment and changes in regimen over time and forecast quantities required for future procurements.

Therefore, it is necessary for the LMIS, which generally focuses exclusively on logistics data, to also collect the total number of patients on treatment by treatment regimen. Patient data and logistics data should be captured on the same LMIS report.

8. In addition to the three essential data items, for HIV tests, collect and report consumption of tests by purpose of testing.

HIV tests can have multiple purposes of testing: for PMTCT, PITC, clinical diagnosis, VCT, and blood safety, among others. In some countries, health workers manage separate registers for different purposes of testing and then aggregate each of these registers to report on a total number of HIV tests dispensed according to purpose of testing. The LMIS for HIV tests may be used to track quantities of HIV tests used by purpose and brand. Capturing these data has significant benefits for program management, especially for monitoring program expansion and forecasting future needs.

The information is also useful for supply chain management. The donation or procurement mechanisms for each of the testing purposes may vary, and maintaining purpose-of-use data can help determine individual requirements during forecasting and with separate reporting requirements. Capturing usage data by purpose of testing can contribute to long-term forecasting by showing trends in proportions by purpose, such as VCT, PMTCT, or clinical diagnosis.

Also, experience has shown that the information summarized by use of test (screening, confirmation, etc.) can be very beneficial for resupply, especially in rapidly expanding programs. These programs may experience supply imbalances, which could force facilities to use nonstandard tests to obtain HIV test results. For example, if facilities have been stocked out of screening or confirmatory tests and have substituted the tie-breaker for that reporting period, the program manager can use the number of tests used for screening, confirmation, and tie-breaker rather than the number of tests by brand to ensure that correct supplies of each brand are issued after the supply situation is corrected.

See the forms in Appendix B, *Daily Log for Usage of HIV Tests and LMIS Report and Request for HIV Tests.*

9. Calculate order quantities using consumption data.

As ART programs and HIV testing programs mature, consumption data should be used to calculate routine resupply commodities for SDPs, whether the calculation is done by the lower level or the higher level. Buffer stocks should be sufficient to cover an increase in the numbers of patients initiated on ART. If the program is rapidly expanding and the increase in demand is uncertain, the system designer should consider increasing the level of buffer stock at the facility.

System designers must determine how many months of consumption data should be averaged and used to calculate order quantities. Systems generally use either one, two, or three months of consumption data. System designers should consider dispensing protocols as well as review periods in making this decision. Many logistics systems for health commodities use three months of consumption data. This option should be considered in cases where the dispensing protocol may call for giving patients more than a review period of supply. In such cases, month-to-month consumption will vary greatly. Using logistics data alone within the max-min system, and assuming monthly reorders and a three-month maximum stock level (one month of dispensing stock, one month of lead time stock, and one month of buffer stock against uncertainty), order quantities would be determined using the standard formula, as follows:

Quantity to Order = (Average Monthly Consumption x 3) – Stock on Hand

In programs where dispensing protocols are standardized, one month's consumption data could be considered. In systems where a two-month review period has been established, two months' consumption data (one review period's data) could be considered. Designers should consider dispensing protocols and review periods to determine how many months' consumption should be used when calculating averages and/or resupply quantities.

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

As with all drugs and other medical supplies, data collected on dispensing registers should be recorded in the smallest unit distributed to clients. For most drugs, the recorded numbers represent numbers of tablets or capsules. Because of the large volumes of drugs dispensed to treat HIV, if an ART program is consistently dispensing drugs to patients as full bottle amounts (i.e., one bottle of syrup or one bottle of tablets is equivalent to a one-month supply) and the package quantities will not be changing, then the bottle can be chosen as the unit for recording.

Because facilities in many countries have large numbers of patients on treatment (more than 1,000), the number of bottles can be a much easier way to report consumption. However, the same unit of measure should be used when reporting other data items (stock on hand, quantities received, losses and adjustments) for products. All products should be reported by either tablet/capsule/ml, or else all products should be reported by bottle. If the same product has multiple pack sizes, the system designer must consider how the LMIS will account for this fact. One consideration is how many pack sizes there are of different products. If there are two pack sizes, data could still be reported by bottle, but they will either have to be reported as separate products or converted to one size for reporting purposes. If there are many different pack sizes, then it may be sensible to report in terms of tablets/capsules/mls.

If the conversion from tablets/capsules/mls into bottles will be done at the facility level, it is important to document this in the system design, and to draft standard operating procedures that direct staff on how that calculation should be done.

11. For HIV tests, determine how the additional consumables required for testing will be resupplied to the testing facility.

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

If there is an established supply chain for laboratory consumables, the system designers should allow that system to ensure the supplies needed for HIV testing. If there is no established supply chain for laboratory consumables, such products could be included in the LMIS for HIV tests to ensure their availability for HIV testing. The system designer should recognize that other commodities besides just the HIV test are needed for administering an HIV test, explore and document the different options for ensuring that these products are available at the SDP level, and determine which system makes the most sense.

In Ghana, there are separate ledgers for each purpose (VCT, PMTCT, quality control, etc.) for HIV testing. The information from the ledgers is used to complete summary reporting.

Refer to *Handbook for Managing Laboratory Supplies* (USAID | DELIVER Project, 2008) for a more complete description.

STORAGE AND DISTRIBUTION OF ARV DRUGS AND HIV TESTS

PURPOSE OF STORAGE AND DISTRIBUTION

The purpose of a storage and distribution system is to ensure the physical integrity and safety of products and their packaging as they move from the central storage facility to SDPs and into the hands of the clients/patients. A sound storage and distribution system will help ensure that products reach the client in usable condition, with minimal loss or waste.

Proper storage procedures help ensure that storage facilities issue only quality products and that there is little or no waste due to damaged or expired products. When all levels of the pipeline follow appropriate storage and distribution procedures, clients can be assured that they have received a quality product.

Acceptable storage facilities (warehouses, storage rooms) are clean and secure, and adequate distribution systems have dependable and secure delivery vehicles. As mentioned earlier, the pipeline should be as short as possible. In the context of storage and distribution, a shorter pipeline can have a positive influence on the security and quality of the products being distributed. Having fewer levels in a system means fewer storage points and fewer instances of transporting products. Limiting the number of times products are transported reduces opportunities for product damage. There are also fewer people handling the products, which can help to increase accountability and minimize loss, damage, and pilferage.

PACKAGING

While the major focus in storage and distribution is on the products being moved, the packaging of the product should also be considered. The packaging provides the primary protection to the product during storage and transportation. The quality of the packaging should be specified during procurement, and sufficient sturdy packaging materials should be available for repackaging products for distribution to lower-level facilities. For protection, products should remain within their sealed outer cartons and/or inner boxes during distribution. This is best achieved by ordering and issuing products to the nearest packing unit quantity. For example, if 48 items are required and 50 items are in an inner box, then 50 should be ordered and distributed. Packaging should be labeled clearly with complete product information, including the expiration date.

GENERAL GUIDELINES FOR STORAGE OF HEALTH COMMODITIES

ARVs and HIV tests should be stored according to a standard set of guidelines that are applicable to all health commodities. Well-functioning warehouses and storerooms at various levels will have sufficient space, acceptable storage conditions, explicit quality assurance mechanisms, and adequate security for the products, and must follow standard storage procedures.

Refer to *The Logistics Handbook* (John Snow, Inc., 2004i) for a more complete description and additional discussion of standard storage guidelines for health commodities.

In Kenya, the national AIDS program began with a distribution system of delivery straight from the central level to the service delivery point. Two years into the program, as more than 90 sites were on board and transportation and resources had trouble coping, the system was redesigned to introduce delivery from the central to the district level, with the service delivery points collecting from the districts.

GENERAL GUIDELINES FOR DISTRIBUTION OF HEALTH COMMODITIES

Health commodities can usually be distributed in one of two ways: a pickup system, where the lower level collects the products at the supplying facility, or a delivery system, where the upper-level supplying facility brings the products to the lower-level receiving facility.

Regardless of the type of distribution mechanism, transportation must be available whenever it is needed to fill regular or emergency orders. This is particularly important in a situation where vehicles are shared for multiple purposes, such as commodity delivery and supervisory visits. In a shared system, supervisory visit activities might take precedence over commodity delivery, which could delay the movement of commodities and result in stockouts at the receiving facility. To the extent possible, dedicated vehicles should be available to transport products.

For all products, procedures should be in place to monitor and document the movement of commodities from the upper levels to the lower levels. The following actions should be completed at each distribution/receipt:

- Verify the type and quantity of products shipped and received.
- Conduct visual inspection, including expiration dates, for quality assurance.
- Complete and sign transaction records/vouchers.
- Store the products.
- Update stock-keeping records.

Never distribute products that are soon to expire and that will not be used before the expiration date. Not only do facilities (or even customers) receive unusable products, but money and resources are wasted in shipping, storing, and handling unusable products.

CHARACTERISTICS OF ARV DRUGS AND HIV TEST KITS THAT AFFECT STORAGE AND DISTRIBUTION

As with the design and implementation of the inventory control and logistics management information systems, certain characteristics of ARV drugs and HIV tests, and how they are used, will affect the methods used for storage and distribution of these commodities. These characteristics include—

- High value in prolonging survival for HIV positive patients
- Higher levels of accountability, including special reporting or other documentation requirements from either donors or manufacturers
- Limited number of sites authorized to use ARV drugs
- Relatively short shelf life that can range from six to 36 months
- For ARVs, significantly high prices relative to most essential medicines
- Cool/cold storage required for some products
- For HIV tests, other commodities needed to administer the test
- In some cases these characteristics may require implementation of a unique procedure for handling ARV drugs or HIV tests, but in other cases increased attention or emphasis should be given to existing procedures. This may be particularly true if ARV drugs or HIV tests are managed within an integrated system.
- ARVs are particularly sensitive to moisture. They should be stored out of direct sunlight in a dry, well-lit, well-ventilated storeroom. In addition, ARVs should not be opened to repackage them.
- Treat ARVs and HIV tests as you would narcotics and controlled substances: provide a secure storage area with controlled and continuous access.
- Maintain cool storage (2°–8°C; 36°–46°F) and cold storage facilities, including cool chain and cold chain, as required.
- Store commodities to facilitate first-to-expire, first-out (FEFO) procedures and stock management.
- Separate damaged, expired, and soon-to-expire commodities from usable commodities, remove them from inventory immediately, and dispose of them using established procedures. Do not issue commodities that could expire before they are distributed to or used by the client.

An additional consideration for ARV drug and HIV test distribution is the increased pressure on the transportation system, due to a possibly more frequent resupply cycle and deliveries to accredited sites only.

RECOMMENDATIONS FOR STORAGE AND DISTRIBUTION OF ARV DRUGS AND HIV TEST KITS

1. Provide appropriate security during storage and distribution.

Storage facilities should have—

Locked storage area(s) within the warehouse or storeroom: Locked storage areas provide an extra level of security; not everyone who enters the storage facility has access to the ARVs or HIV tests. A locked room or vault, secure cage, or other structure can be installed within the warehouse, or a locked cabinet or armoire can be installed in a smaller storeroom. If cool storage facilities are not already locked and tightly controlled, then a more secure area inside the cooler should be installed as well. The warehouse or storeroom itself should be robust in structure, with no openings or weaknesses in the walls or roof that would allow easy entry after hours.

Limited access to HIV and AIDS commodities: The number of people who are allowed to access the secure storage area should be limited. However, systems must be in place to ensure that someone with access is always available for filling regular or emergency orders.

Higher level of accountability: Because of their high price and high value, ARV drugs and HIV tests should be treated as controlled substances. In most cases, procedures for controlled substances should include a second signature on the stock-keeping and transaction records for each stock movement. Requiring the signature of someone in addition to the storekeeper who is responsible for storing and distributing the product helps protect the both product and the storekeeper.

Physical inventories: Monthly physical inventories should be conducted for ARV drugs and HIV tests, whether or not the review period has been established as monthly.

Transport should have the same level of security as the product in storage. Vehicles used to transport high-value commodities must be secure, with an enclosed bed and locking doors. For personal security, drivers should be equipped with radios and be in frequent communication with their dispatchers while on delivery. In some cases, depending on the quantities of commodities being transported or past incidence of theft, it even be necessary to provide armed guards or other supplemental security measures.

2. Adhere to first-to-expire, first-out procedures.

Because of the short shelf life and high cost of ARV drugs and HIV tests, special care must be taken to follow FEFO stock management and to monitor product expiration dates to ensure that products are used before expiration to reduce waste. In addition, commodity managers must take action immediately if there is a risk that products will expire before they can be used. Action may include returning the products to the supplying facility for redistribution or directly transferring the products to a facility that can use them before they expire and notifying the procurement and program management units.

> Remember that expiration dates are based on products being stored under ideal storage conditions. If a facility does not maintain adequate storage conditions, products may become unusable before their posted expiration date.

3. Ensure product integrity if reissuing returned drugs.

In an ART program, excess supplies of drugs may be returned by patients who have switched treatment regimens, or by a patient's family in the event of the patient's death. Although pharmaceutical guidelines around drug contamination must be respected, in some programs these drugs may be reissued to other patients. If reissuing occurs, these drugs must first be inspected. If the product's packaging shows no signs of tampering or damage, and the product is not close to expiry, it can be reissued to another patient.

4. Consider outsourcing storage and distribution as a way of strategically managing your resources.

Many HIV treatment and testing programs are conducted in resource-limited settings. When a program has limited resources to devote to directly strengthening the country's own logistics system, outsourcing storage and distribution to private companies should be considered. Maintaining appropriate warehouse conditions or structurally improving an existing warehouse can be an expensive endeavor outside the reach of many programs. Private warehousing companies should be considered as a viable alternative.

Depending on the number of sites to which commodities are being delivered and other available resources, it can be advantageous to use local courier or express mail (post office, DHL) services to distribute ARV drugs. If the number of sites is extremely limited, it may be much less expensive to distribute products through these channels, rather than maintaining vehicles and the personnel to operate them. However, keep in mind that couriers must also be able to maintain product safety and follow security guidelines, including cool storage for products that require it. The program is responsible for monitoring courier performance.

APPENDIX A

KAAMANLAND HIV AND AIDS PROGRAM ARV DRUG AND HIV TEST SUPPLY CHAINS: A CASE STUDY

This case study describes the supply chains for ARV drugs and HIV tests for the HIV and AIDS program in the imaginary country of Kaamanland. It provides a context in which to review the records and reports that follow.

Although Kaamanland is imaginary, the supply pipeline, inventory control system, and LMIS described are based on actual management systems to which DELIVER provides assistance. The following pipeline diagrams and LMIS forms illustrate recommended inventory control and LMISs and are consistent with the recommendations of this document.

KAAMANLAND ART PROGRAM AND SUPPLY CHAIN

In Kaamanland, ART is currently provided at 50 sites—central-level hospitals, regional hospitals, and a few district hospitals. Within the next year, ART services will be expanded and available in all district hospitals, as well as designated ART follow-up sites (urban clinics). At that point, ART will be available at 80 sites.

ARV drugs are procured internationally by the Ministry of Health and are donated by international donors. Forecasting and quantification are done by program management. ARV drugs are stored in the central medical stores, which deliver drugs directly to ART sites monthly.

The inventory control system is a pull system that uses the forced ordering maximum-minimum version. ARV drugs are stored with other essential drugs in the central medical stores, but distribution of ARV drugs is not integrated with any other health commodity distribution.

ART sites use the *ARV Drug Dispensing Register* to record the quantity of each drug given to patients in the dispensing area and to capture the total numbers of patients on ART by treatment regimen. Stock Cards are used to record stocks received and issued, losses and adjustments, and stock on hand for ARV drugs stored at the service site.

The ART service provider uses the *ARV Drug Dispensing Register* and the *Stock Cards* to complete the *LMIS Report and Request for Antiretroviral Drugs*. The report and request is sent to the Logistics Management Unit of the Ministry of Health, where the information is compiled with reports from

other ART sites. Within two days of receipt, the compiled orders are sent to the Central Medical Stores for processing and delivery. After all LMIS reports have been received, the Logistics Management Unit generates logistics reports on ART sites and central warehouse activities, which are sent to program management for action as needed. Program managers use current information on national stock status and consumption to update quantification of drug needs, procurement plans, and shipping schedules with external suppliers.

KAAMANLAND HIV TEST PROGRAM AND SUPPLY CHAIN

In Kaamanland, HIV testing is conducted in a variety of settings, including PITC at all health facilities; VCT centers; and clinics that offer PMTCT services.

HIV test kits are procured internationally by the Ministry of Health and are donated by international donors. Forecasting and quantification are done by program management. HIV tests are stored at the National Reference Laboratory and delivered directly to HIV testing sites monthly. The inventory control system is the delivery truck, forced ordering maximum-minimum version. HIV test kit distribution is not integrated with any other health commodity distribution.

HIV testing sites use the *Daily Log for Usage of HIV Tests* to record the quantity of each test administered to patients and its use in the testing algorithm. Although all HIV tests are conducted in the laboratory, separate logs are maintained for HIV testing for PITC, VCT, and PMTCT.

Stock Cards are used to record stocks received and issued, losses and adjustments, and stock on hand for HIV tests stored at the testing site. At the end of each month, the laboratory personnel or providers managing the HIV tests use the *Daily Log for Usage of HIV Tests* and the *Stock Cards* to complete the *LMIS Report and Request for HIV Tests*. The report and request is then given to the HIV test delivery team when it arrives at the testing site on a designated day of the following month. During the delivery team visit, data are checked and the HIV tests are issued to the testing site. On the team's return to the capital, the reports are submitted to the Logistics Management Unit of the Ministry of Health, where the information is compiled. After all LMIS reports have been received, the Logistics Management Unit generates logistics reports on HIV testing sites and the National Reference Laboratory and sends to program management for action as needed. Program managers use current information on national stock status and consumption to update the quantification of test kit needs, procurement plans, and shipping schedules with the external suppliers.

Figure 1. Kaamanland ARV Drug Pipeline

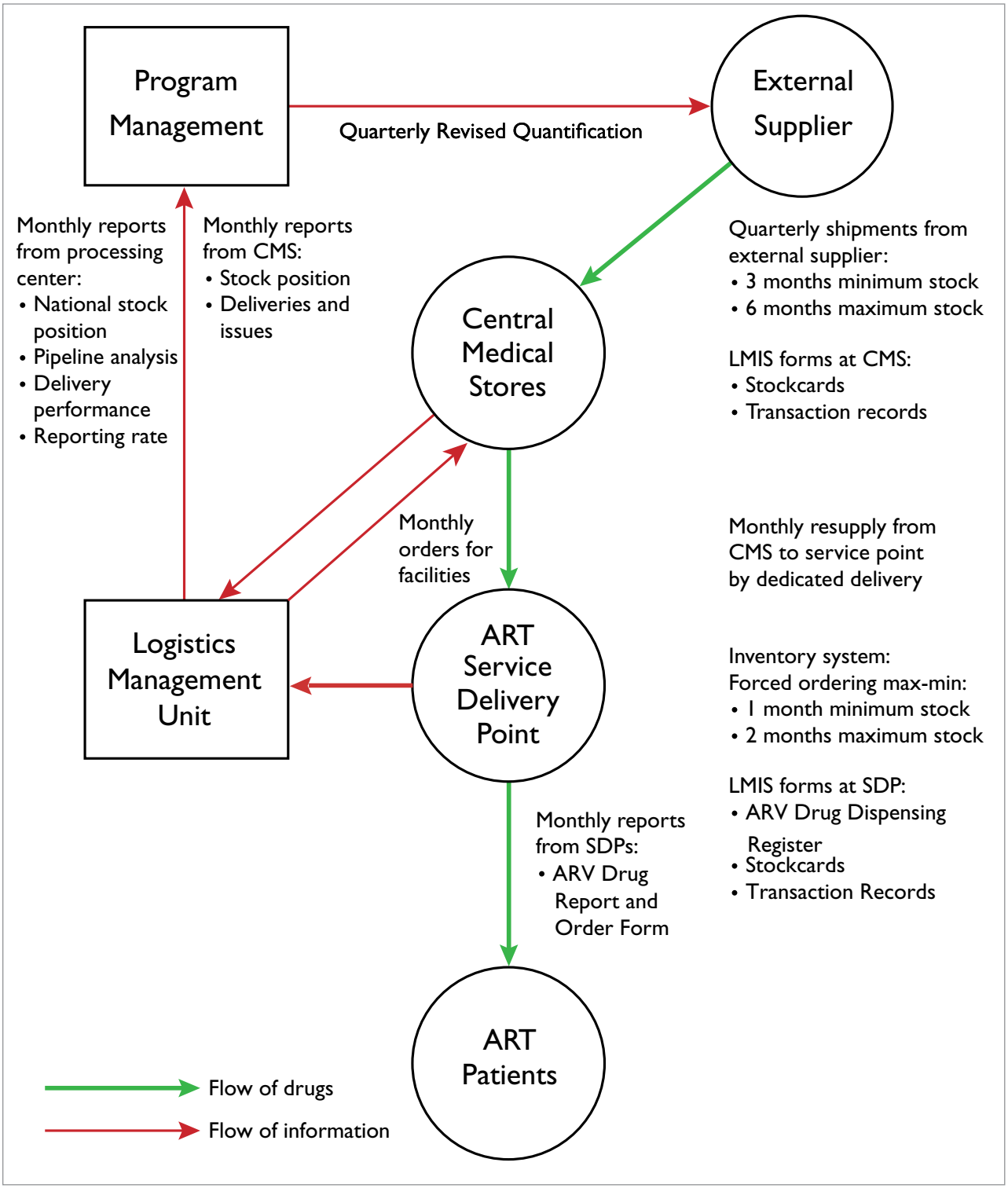
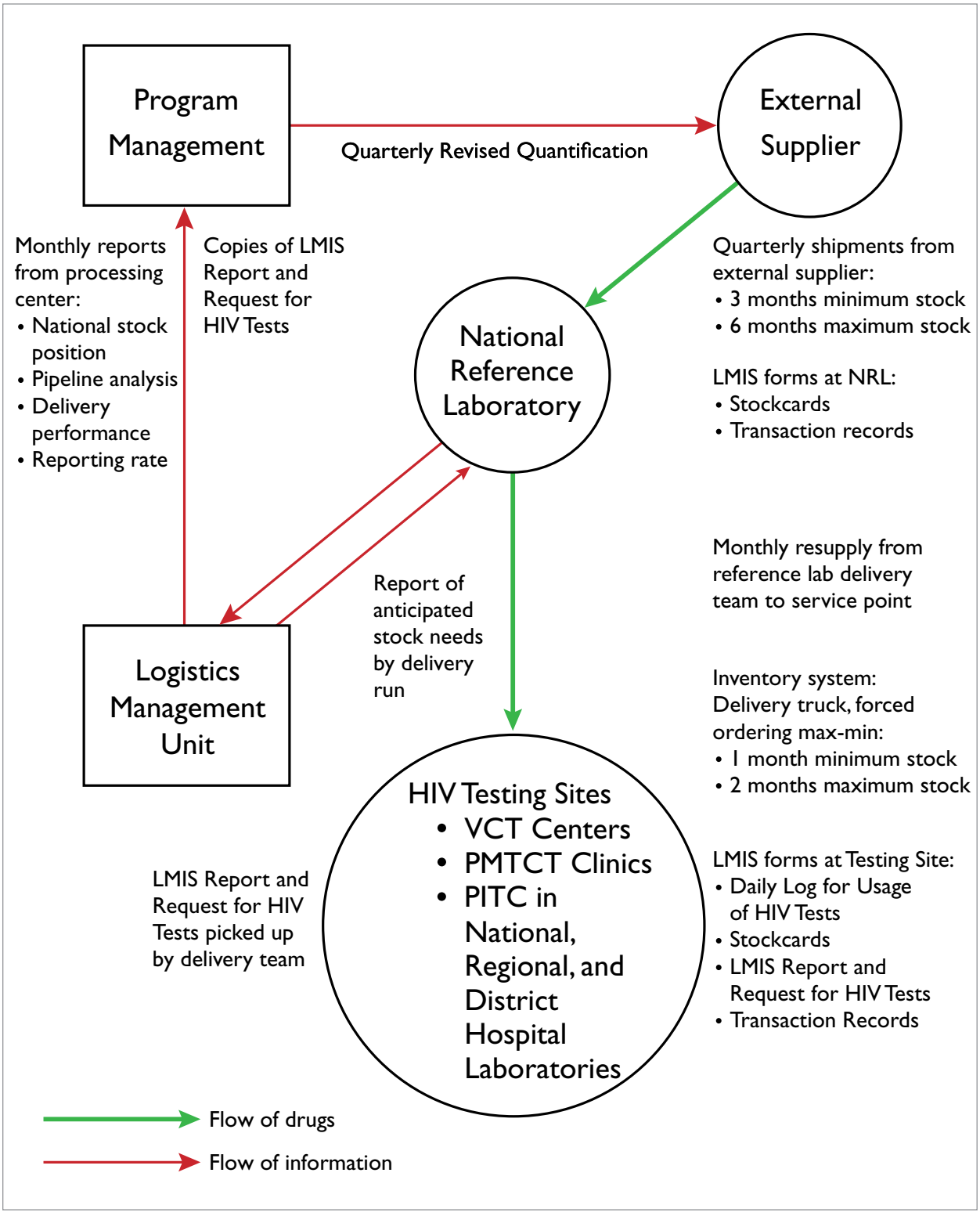


Figure 2. Kaamanland HIV Test Pipeline



APPENDIX B

RECORDS AND REPORTS FOR MANAGING ARV DRUGS AND HIV TESTS

Note: The sample forms included here are for illustrative purposes only. They were designed to complement the written guidelines and recommendations in the guide. The forms illustrate how the recommendations come together in the form of LMIS records and reports, which can then be used by a country program. For this example, the forms represent a system with a **monthly** reporting and ordering frequency and include only a subset of ARV drugs, rather than the comprehensive list of ARV drugs for all regimens. While the forms may be directly applicable in a country program, some modification will be necessary, depending on program-specific requirements or characteristics (e.g., maximum stock levels, treatment protocols/testing algorithms). Nevertheless, the sample forms do reflect the recommendations and guidelines indicated throughout this guide. The preprinting of commodity names, units, and the like, on forms should be customized to each country or program setting and should reflect the selected standard treatment or testing guidelines. Other records, which are not included in the sample or listed below but which are **critical** for an effective LMIS and country programs, include stock-keeping records (e.g., stock cards, bin cards) that track information on commodities in the storeroom, and transaction records (e.g., issue vouchers, packing slips) that track movement of commodities between different levels in the system.

ARV Drug Dispensing Register: This consumption record is used to track ARV drugs; it is maintained by the service providers who dispense drugs to patients. This record is also used to track the total number of ART patients by regimen at a facility. The quantities of ARV drugs dispensed feed into the monthly consumption totals and are used to determine average monthly consumption and reorder quantities on the *LMIS Report and Request for Antiretroviral Drugs*. The total number of ART patients by regimen is aggregated and feeds into the *LMIS Report and Request for Antiretroviral Drugs*.

LMIS Report and Request for Antiretroviral Drugs: This is a combined logistics report and transaction record/order form for ARV drugs. It provides a full report of all three essential logistics data and demonstrates the order quantity calculations. The report is submitted to the supplier and shared with program staff.

Daily Log for Usage of HIV Tests: This consumption record tracks the use of HIV tests by purpose of use (VCT, PMTCT, clinical diagnosis), by brand, and by use of test (screening, confirmatory, or tiebreaker). The service provider who conducts HIV testing maintains the log. The quantities recorded by brand feed into the monthly usage totals and are used to determine average monthly usage and reorder quantities.

LMIS Report and Request for HIV Tests: This combined logistics report and transaction record/order form is used for HIV tests. It provides a full report of the three essential logistics data items and demonstrates the order quantity calculations. It also includes summary use data divided by purpose and use of test. The report is submitted to the supplier and shared with the program staff.

Figure 3. Interrelationships between LMIS Records and Reports for ARV Drugs

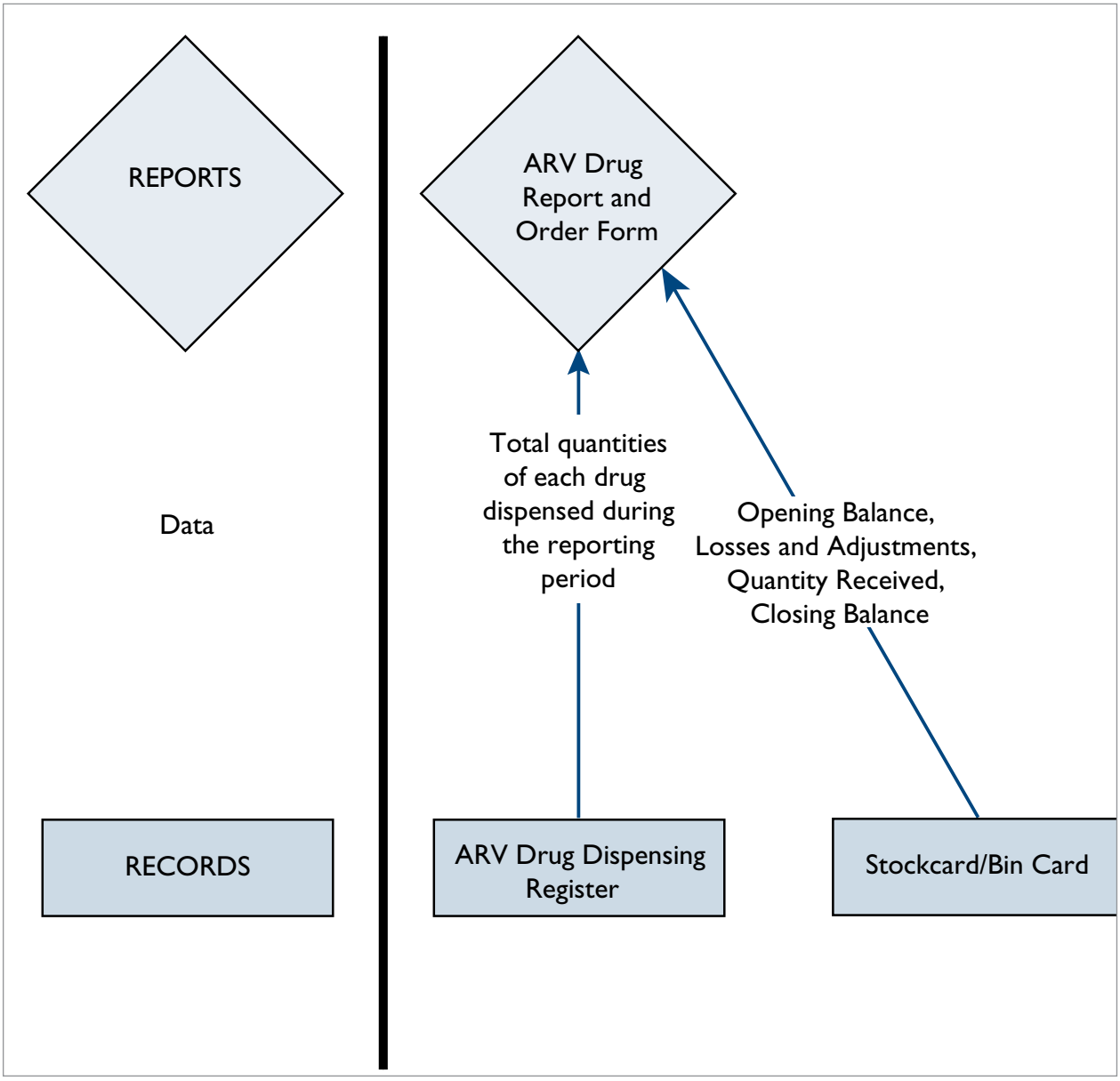
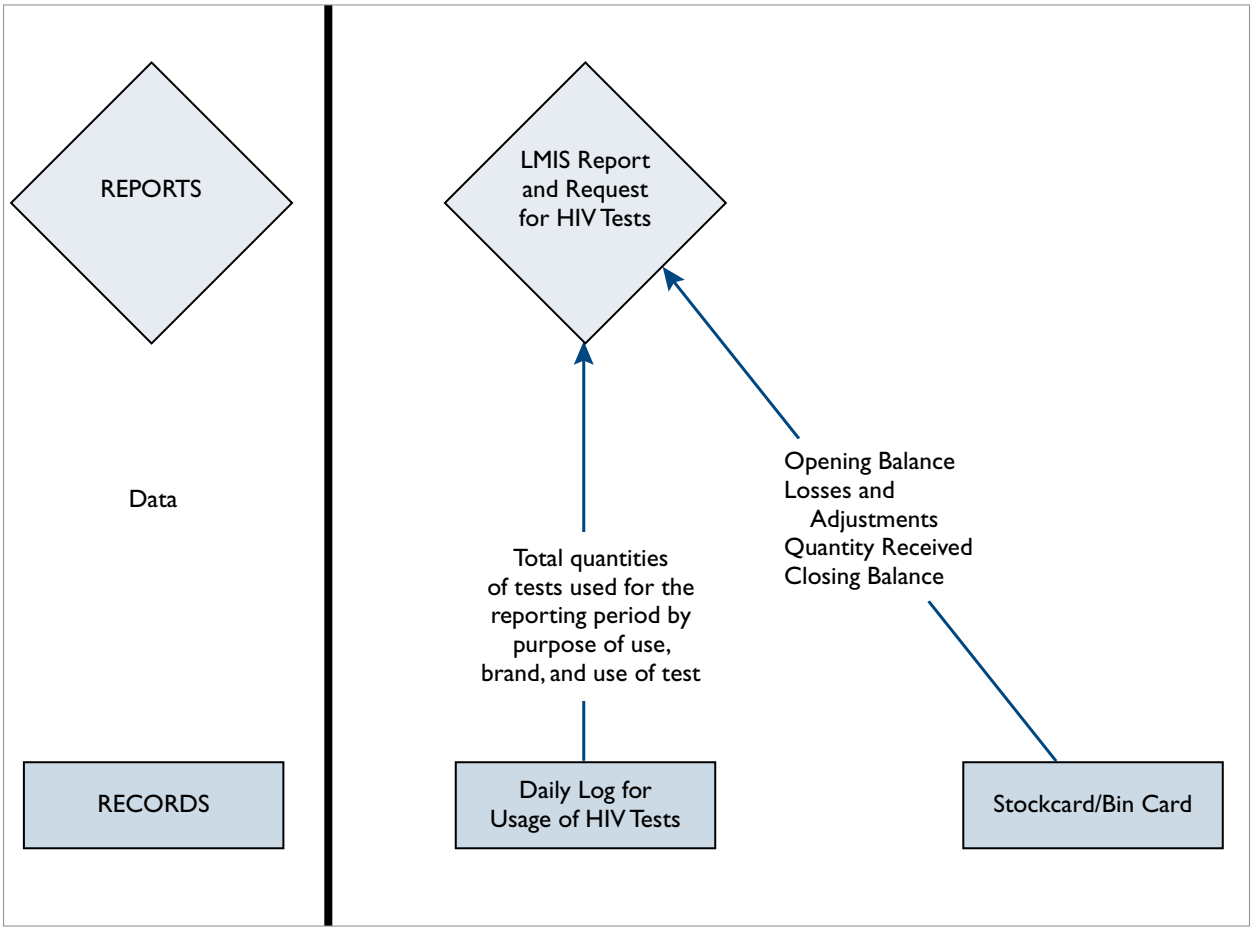


Figure 4. Interrelationships between LMIS Records and Reports for HIV Tests



ARV Daily Dispensing Register

Adult ARV Drugs

Date	Patient Clinic ID Number	First visit during this reporting period? (if yes, tick below)	First Line Regimen (tick appropriate regimen ONLY IF first visit this reporting period)				Second Line Regimen (tick appropriate regimen ONLY IF first visit this reporting period		Stavudine//Lamivudine	Stavudine/Lamivudine / Nevirapine	Zidovudine/ Lamivudine	Zidovudine /Lamivudine /Nevirapine	Efavirenz	Nevirapine	Tenofovir	Lopinavir/ Ritonavir				Signature
			1	2	3	4	1	2	30/150mg	30/150/200mg	300/150mg	300/150/200mg	600mg	200mg	300mg	200/50mg				
									Tablets	Tablets	Tablets	Tablets	Tablets	Tablets	Tablets	Tablets				
Page Totals																				
Running monthly Totals																				

Regimen Key:

First Line

1 = stavudine+lamivudine+nevirapine; 2 = stavudine+lamivudine+efavirenz; 3 = zidovudine+lamivudine+nevirapine; 4 = zidovudine+lamivudine+efavirenz

Second Line

1= tenofovir+lopinavir/ritonavir+efavirenz 2= tenofovir+lopinavir/ritonavir+nevirapine

ARV Drug Daily Dispensing Register
Pediatric ARV drugs

Date	Patient Clinic ID Number	First visit during this reporting period? (if yes, tick below)	Regimen (tick appropriate regimen ONLY IF first visit this reporting period)						Zidovudine	Lamivudine	Nevirapine	Stavudine/Lamivudine	Stavudine/Lamivudine/ Nevirapine	Stavudine/Lamivudine	Stavudine/Lamivudine/ Nevirapine	Efavirenz	Efavirenz	Zidovudine	Abacavir	Didanosine	Didanosine	Lopinavir/Ritonavir				Signature
			1	2	3	4	5	6	50mg/5ml Solution	50mg/5ml Solution	50mg/5ml Solution	6/30mg Tablets	6/30/50mg Tablets	12/60mg Tablets	12/60/100mg Tablets	50mg Tablets	200mg Capsules	100mg Capsules	20mg/ml Solution	25mg Tablets	50mg Tablets	80/20mg/ml Solution				
Page Totals																										
Running Monthly Totals																										

Regimen Key:

1 = stavudine+lamivudine+nevirapine; 2 = stavudine+lamivudine+efavirenz; 3 = zidovudine+lamivudine+nevirapine; 4 = zidovudine+lamivudine+efavirenz; 5 = zidovudine+didanosine+lopinavir/ritonavir; 6 = abacavir+didanosine+lopinavir/ritonavir

Ministry of Health
ARV Drug Report and Order Form

SECTION A: FACILITY IDENTIFIER AND REPORTING PERIOD

REPORTING HEALTH FACILITY:					CODE:	
DISTRICT:					CODE:	
PROVINCE:					CODE:	
REPORTING PERIOD START:	Day:		Month:		Year:	
REPORTING PERIOD END:	Day:		Month:		Year:	

SECTION B: PATIENT DATA

Adult Treatment Regimens			Pediatric Treatment Regimens (Patients on pediatric formulations ONLY)		
		No. of patients on this regimen at the end of the reporting period			No. of patients on this regimen at the end of the reporting period
First Line			*First Line*		
B1	Stavudine 30mg + Lamivudine 150mg + Nevirapine 200mg		B7	Stavudine + Lamivudine + Nevirapine	
First Line Alternatives			*First Line Alternatives*		
B2	Stavudine 30mg + Lamivudine 150mg + Efavirenz 600mg		B8	Stavudine + Lamivudine + Efavirenz	
B3	Zidovudine 300mg + Lamivudine 150mg + Nevirapine 200mg		B9	Zidovudine + Lamivudine + Nevirapine	
B4	Zidovudine 300mg + Lamivudine 150mg + Efavirenz 600mg		B10	Zidovudine + Lamivudine + Efavirenz	
Second Line			*Second Line*		
B5	Tenofovir 300mg + Lopinovir/ritonavir 200/50mg + Nevirapine 200mg		B11	Abacavir + Didanosine + Lopinavir/ritonavir	
B6	Tenofovir 300mg + Lopinovir/ritonavir 200/50mg + Efavirenz 600mg		B12	Zidovudine + Didanosine + Lopinavir/ritonavir	

SECTION C: Consumption/Requisition

		A Remaining qty from last report period	B Qty received during reporting period	C Qty dispensed during reporting period	D Losses and Adjustments			E Qty remaining *(Physical count)*	F Qty requested (Cx2)-E	G Qty approved *(For official use)*
					Damaged/ lost	Expired	Transferred In(+)/Out(-)			
Adult ARV Drugs *(Report by bottle)*										
C1	Stavudine/Lamivudine 30/150mg tablets (Bottle of 60)									
C2	Stavudine/Lamivudine/Nevirapine 30/150/200mg tablets (Bottle of 60)									
C3	Zidovudine/Lamivudine 300/150 tablets (Bottle of 60)									
C4	Zidovudine/Lamivudine/Nevirapine 300/150/200mg tablets (Bottle of 60)									
C5	Zidovudine/Lamivudine 300/150mg tablets (Bottle of 60)									
C6	Nevirapine 200mg tablets (Bottle of 60)									
C7	Efavirenz 600mg tablets (Bottle of 30)									
C8	Zidovudine 300mg tablets (Bottle of 60)									
C9	Lopinavir/ritonavir 200/50mg tablets (Bottle of 120)									
C10	Tenofovir 300mg tablets (Bottle of 30)									
C11										
C12										
C13										
Pediatric ARV Drugs *(Report by bottle)*										
C14	Stavudine/Lamivudine 6/30mg tablets (Bottle of 60)									
C15	Stavudine/Lamivudine 12/60mg tablets (Bottle of 60)									
C16	Stavudine/Lamivudine/Nevirapine 6/30/50mg tablets (Bottle of 60)									
C17	Stavudine/Lamivudine/Nevirapine 12/60/100mg tablets (Bottle of 60)									
C18	Lamivudine solution 50mg/5ml (100ml Bottle)									
C19	Nevirapine solution 50mg/5ml (100ml Bottle)									
C20	Zidovudine solution 50mg/5ml (100ml Bottle)									
C21	Efavirenz 50mg capsules (Bottle of 30)									
C22	Efavirenz 200mg capsules (Bottle of 30)									
C23	Zidovudine 100mg tablets (Bottle of 100)									
C24	Didanosine 25mg tablets (Bottle of 60)									
C25	Didanosine 50mg tablets (Bottle of 60)									
C26	Lopinavir/ritonavir solution 20/80 mg/ml (300ml Bottle)									
C27	Abacavir solution 20mg/ml (240ml Bottle)									
C28										
C29										
C30										

SECTION D: STOCKOUTS

Line Code	Description	Duration (Days)

SECTION E: COMMENTS

SECTION F: SIGNATURES

Compiled by:	Name and Title:	Date:
	Signature:	
Approved by:	Name and Title of Supervisor/ Head of Institution:	Date:
	Signature:	

Facility Stamp:

Received at Provincial office by ……..**Date**……/……../……

Received at Logistics Sub-Unit by……..**Date**……/……../……..

Approved at Logistics Sub-Unit by ……..**Date**……/……../……

Sent to central warehouse by……..**Date**……/……/……

DAILY LOG FOR USAGE OF HIV TESTS

Purpose of HIV Tests (check one box for each register)

- ☐ VCT
- ☐ PMTCT
- ☐ Clinical Diagnosis
- ☐ Blood Safety
- ☐ Sentinel Surveillance
- ☐ Other: _____

Facility: _____ District: _____

Date	Client Name/Number	Determine			Uni-Gold			Bionor			Other		
		S	C	T	S	C	T	S	C	T	S	C	T
Total usage based on use of test:													
Total usage by brand:													
Total usage by brand for the month (running total):													

Summary of Use of Tests:		
Use of Test	**Total**	**Total for the Month (running total)**
Screening:		
Confirmatory:		
Tie breaker:		

Legend
S = Screening
C = Confirmatory
T = Tie breaker

LMIS REPORT AND REQUEST FOR HIV TESTS

Reporting Period: From _____ to _____
mm/dd/yyyy

Maximum Stock Level: 2 Months

Facility: _____ mm/dd/yyyy _____ District: _____

Minimum Stock Level: 1 Months

HIV Test	Basic Unit	Opening Balance	Quantity Received	Losses/ Adjustments	Quantity Used	Closing Balance	Maximum Stock Quantity	Quantity Needed
		A	B	C	D	E = [(A + B) +/- C] - D	F = D x 2	G = F - E
Determine	Test							
Uni-Gold	Test							
Bionor	Test							
Other	Test							
	Test							

Remarks and explanations of losses/adjustments:

Summary of Usage of HIV Tests by Purpose, Brand, and Use of Test						
	VCT	PMTCT	Clinical Diagnosis	Blood Safety	Other	Totals
Determine						
Uni-Gold						
Bionor						
Other						
Total Screening						
Total Confirmatory						
Total Tie breaker						

Prepared by: _____ _____ _____ _____

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