GUIDELINES FOR MANAGING THE HIV/AIDS SUPPLY CHAIN
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The author's views expressed in this publication do not necessarily reflect the views of the United States Agency for International Development or the United States Government.
DELIVER

DELIVER, a six-year worldwide technical assistance support contract, is funded by the President’s Emergency Plan for AIDS Relief (PEPFAR) through the U.S. Agency for International Development (USAID).

Implemented by John Snow, Inc. (JSI), (contract no. HRN-C-00-00-00010-00) and subcontractors (Manoff Group, Program for Appropriate Technology in Health [PATH], and Social Sectors Development Strategies, Inc.), DELIVER strengthens the supply chains of health and family planning programs in developing countries to ensure the availability of critical health products for customers. DELIVER also provides technical management of USAID’s central contraceptive management information system.

Recommended Citation


Abstract

Comprehensive national HIV/AIDS programs are relative newcomers to public health programs in resource limited settings. Recent global initiatives such as the President’s Emergency Plan for AIDS Relief; the Global Fund for HIV/AIDS, Tuberculosis, and Malaria; the Clinton Foundations HIV/AIDS Initiative; and WHO’s 3 by 5 Strategy have fostered an environment of rapid expansion of HIV/AIDS programs in countries by focusing financial, human, and technical resources toward achieving global prevention, care, and treatment goals. As a result, in many countries, the life cycle of these HIV/AIDS programs is somewhat distorted by the political, multilateral, bilateral, and social pressure to rapidly scale up these services, and program implementation is not as systematic as managers would prefer.

Frequently, implementation of HIV/AIDS supply chains occurs in a context where programs are simultaneously expanding and maturing. This concurrent pressure on programs to both evolve toward maturity and rapidly scale up, poses several challenges for the development of supply chain management systems. Also, in many countries most affected by the HIV/AIDS epidemic, the capacity of public health commodity supply chains to ensure a reliable supply of the products needed at service delivery sites is already limited; this constitutes a further challenge.

The Guidelines for Managing the HIV/AIDS Supply Chain is a set of references for managers working to ensure a continuous supply of quality HIV/AIDS commodities to programs. The Guidelines highlight lessons learned from JSI and DELIVER advisors experience designing, implementing, and improving HIV/AIDS supply chains in resource limited settings. The recommendations and tools presented in the Guidelines have been developed specifically for programs where supply chain implementation is occurring within the context described above. The authors recognize that as HIV/AIDS programs continue to evolve, so will supply chain solutions. The Guidelines will be updated accordingly.
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PROCURING HIV/AIDS COMMODITIES USING U.S. GOVERNMENT FUNDS: LESSONS AND APPROACHES

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HIV/AIDS SERVICE DELIVERY PROGRAMS: OVERVIEW AND INSIGHTS FOR SUPPLY CHAIN MANAGERS
BUILDING BLOCKS FOR INVENTORY MANAGEMENT OF HIV TESTS AND ARV DRUGS

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

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Recommended Citation


Abstract

Securing a dependable, uninterrupted supply of antiretroviral (ARV) drugs and HIV test kits is critical to the success of HIV testing and treatment programs. Toward this goal, a robust logistics system, supported by sufficient infrastructure, is needed to manage commodities and to strengthen the entire supply chain. ARV drugs and HIV tests, two products that are new to public health logistics systems, have special management needs.

This document focuses on four elements of supply chain and pipeline management: the inventory control system, the logistics management information system, storage, and distribution. These four elements require special consideration in the context of supply chain management of ARV drugs and HIV tests. Luxuries typically built into supply chains, which relieve pressure on those managing the system, may lead to wasted financial and product resources when managing these commodities. Because of these challenges, this paper makes recommendations that follow guiding principles and lessons learned from DELIVER’s experience that have proven effective in supply chain management of ARV drugs and HIV tests.

DELIVER

John Snow, Inc.
1616 North Fort Myer Drive, 11th Floor
Arlington, VA 22209 USA
Phone: 703-528-7474
Fax: 703-528-7480
Email: deliver_project@jsi.com
Internet: deliver.jsi.com
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<th>Description</th>
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<td>AIDS</td>
<td>acquired immunodeficiency syndrome</td>
</tr>
<tr>
<td>ART</td>
<td>antiretroviral therapy</td>
</tr>
<tr>
<td>ARV</td>
<td>antiretroviral drugs</td>
</tr>
<tr>
<td>CMS</td>
<td>central medical stores</td>
</tr>
<tr>
<td>FEFO</td>
<td>first-to-expire, first-out</td>
</tr>
<tr>
<td>HIV</td>
<td>human immunodeficiency virus</td>
</tr>
<tr>
<td>HMIS</td>
<td>health management information system</td>
</tr>
<tr>
<td>LMIS</td>
<td>logistics management information system</td>
</tr>
<tr>
<td>NRL</td>
<td>National Reference Laboratory</td>
</tr>
<tr>
<td>PMTCT</td>
<td>prevention of mother-to-child transmission</td>
</tr>
<tr>
<td>SDP</td>
<td>service delivery point</td>
</tr>
<tr>
<td>STG</td>
<td>standard treatment guidelines</td>
</tr>
<tr>
<td>VCT</td>
<td>voluntary counseling and testing</td>
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<td>WHO</td>
<td>World Health Organization</td>
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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/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/AIDS services. The publication is also dedicated to friends and counterparts who have worked with DELIVER, 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/AIDS and laboratory commodities, we recognize that comprehensive HIV/AIDS and laboratory programs require the supply chain to manage and deliver a broad range of several hundred public health commodities.

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EXECUTIVE SUMMARY

INTRODUCTION
A logistics system that manages any health commodity, antiretrovirals (ARVs), HIV tests, or others, must have the infrastructure to manage and move commodities that support the supply chain as a whole. This document focuses on four elements of supply chain and pipeline management: (1) the inventory control system, (2) the logistics management information system, (3) storage, and (4) distribution. These four elements, in particular, require special consideration in the context of supply chain management of ARV drugs and HIV tests.

While it is highly desirable for all supply chains to be as effective and as efficient as possible, the need for effectiveness and efficiency is even more important when ARV drugs and HIV tests are being managed. Luxuries typically built into supply chains, which relieve pressure on those managing the system, may lead to wasted financial and product resources when managing these commodities. The following discussions and recommendations for managing ARVs and HIV tests assume that the basic elements of a performing supply chain are already in place or can readily be put into place.

SPECIAL CHARACTERISTICS OF ARV DRUGS AND HIV TESTS
ARV drugs and HIV tests, two products that are new to public health logistics systems, have particular characteristics that influence how they are managed. Compared to many other essential medicines, ARVs and HIV tests 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.

SPECIAL CHARACTERISTICS OF ARV DRUGS AND HIV TESTS INCLUDE—
• short shelf life that can range from six to 24 months
• high price, including a significant jump in price when moving from first line antiretroviral therapy (ART) to alternate treatment regimens
• cool storage required for some products
• treatment and testing protocols that require multiple products from multiple sources to be available simultaneously to provide a service
• dynamic technology for products leading to constantly evolving treatment and testing protocols

When providers do not have consistent supplies of ARVs because of non-functioning supply chains, treatment can be severely compromised, given that providers prescribe ARV drugs in combinations that can be toxic, lethal, or ineffective for antiretroviral therapy (ART). In one country, patients were being treated according to the six following combinations of drugs, none of which were included in the local standard treatment guidelines (STGs) or WHO-recommended STGs:

- ABC/AZT/3TC
- AZT/ddI/NVP
- d4T/3TC/IDV
- d4T/3TC/NLF
- d4T/ddI/NLF
- 3TC/AZT/IND
• higher levels of accountability, including special reporting or other documentation requirements from either donors or manufacturers
• greater potential for redistribution of products from one facility to another
• limited number of sites authorized to use the products
• limited possibility for substitution in the case of stockouts.

**SPECIAL CHARACTERISTICS OF ARV DRUGS INCLUDE—**
• high value in prolonging survival for AIDS patients
• need for continued, uninterrupted resupply for patients already on ART
• special ordering and information requirements for second line and alternate drug treatment if these drugs are not kept routinely at the service site.

**SPECIAL CHARACTERISTICS OF HIV TEST KITS INCLUDE—**
• other commodities needed for administration
• kit contents and packaging considerations (e.g., number of tests per kit, inclusion of chase buffer, different expiration dates for tests and buffer).

**RECOMMENDATIONS**
The following recommendations are guiding principles and lessons learned from DELIVER’s experience that have proven effective in supply chain management of ARVs and HIV tests.

**INVENTORY CONTROL SYSTEM**
• Reduce the length of the supply pipeline.
• Use the forced ordering version of the maximum-minimum (max-min) inventory control system.
• Implement a monthly reporting period and order cycle.
• In a new program, phase in the inventory control system for second line drugs at facilities.
• Implement a mechanism for returning products for rapid redistribution before expiry.

**LOGISTICS MANAGEMENT INFORMATION SYSTEM**
• Link routine reporting to commodity ordering.
• Avoid overburdening the logistics management information system (LMIS) by collecting excessive service statistics or other data that do not have direct benefit to the management of commodities.
• Always collect and report dispensed-to-user data for ARVs and usage data for HIV tests; do not use issues data as a proxy.
• Refrain from altering the content and formatting of the LMIS to accommodate the funding mechanism.
• Convert quantities to issue of ARVs and HIV tests from units to packs at the issuing level, not the ordering level.
**LMIS FOR ARVS**
- In addition to the three essential logistics data items, limit the amount of patient data that are collected and reported to the number of new and existing patients by treatment regimen. Use these data for decision making.
- If program reporting captures estimates of new patients, provide worksheets to translate patient numbers into product numbers.
- Select and consistently use one unit for recording drugs.
- Separate clinical/program information used for program monitoring, data collected from logistics, and patient data collected for logistics decisions.

**LMIS FOR HIV TESTS**
- In addition to the three essential logistics data items, limit other data collected and reported through the LMIS. Do track usage of HIV tests by purpose of use, brand, and use of test.
- Use the individual test as the unit for recording.
- Manage test-related supplies through the existing system for laboratory supplies.

**STORAGE AND DISTRIBUTION**
- When feasible, integrate the storage and distribution of ARV drugs and HIV tests.
- Provide greater security during storage.
- Ensure increased security during transport.
- Pay special attention to first-to-expire, first-out.
- Ensure product integrity if reissuing returned drugs.
- Deliver ARV drugs and HIV tests to accredited sites only.
- Consider using private or other courier/express mail facilities.
- Ensure that products used together are distributed together.
A logistics system that manages any health commodity, ARVs, HIV tests, or otherwise, must have established infrastructure to manage and move commodities, all of which supports the supply chain as a whole. This infrastructure includes:

- A commodity resupply pipeline
- An information system for gathering and using commodity data
- Storage facilities
- 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 part of the logistics system for ARV drugs and HIV tests, 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.

Securing a dependable, regular supply of ARV drugs or HIV tests at service delivery points is critical to the success of antiretroviral therapy (ART) programs and laboratory diagnosis. Any interruption in the supply chain will prevent diagnosis of new patients or endanger the lives of those patients already on therapy due to risk of discontinuation of treatment or development of drug resistance. Frequent interruptions could lead to failure of the program.

The following discussions about and recommendations for managing ARVs and HIV tests assume that the basic elements of a performing supply chain are already in place or can be put into place. Additional requirements or particular application of the basic elements will be needed based on the special nature of ARV drugs and HIV tests.

Refer to *The Logistics Handbook* for basic guidance on supply chain design and implementation.
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 only be guaranteed through the selection, design, and proper implementation of an appropriate inventory control system. A number of strategies or inventory control systems can be adopted to manage commodities of any kind. Some of these, such as a rationing system, are more appropriate in situations where the product supply being managed, or the financial resources available to purchase the products being managed, is unsure. In a traditional rationing system, supplies are allocated based on 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 so 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 target number of patients, at least in the short term. To manage full-supply products effectively, a maximum-minimum inventory control system (also known as a max-min system) is recommended.

MAXIMUM-MINIMUM INVENTORY CONTROL SYSTEMS

FULL SUPPLY SITUATION
Implementation of a maximum-minimum (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], 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 developing 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 available 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, service delivery points 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/re-supplied 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 has been distributed, i.e., at the end of the reporting period, a new bin is re-supplied 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/re-supplied to the maximum stock level.

Refer to *The Logistics Handbook* for more a 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 staff adequately at the lower levels) 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, would choose a push system. In either case, adequate information and data have to be available; see Logistics Management Information Systems section for further discussion of this topic.

**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 24 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*.

<table>
<thead>
<tr>
<th>Level</th>
<th>Lead Time Stock Level</th>
<th>Safety Stock Level</th>
<th>Review Period/Order Interval</th>
<th>Min</th>
<th>Max</th>
<th>Emergency Order Point</th>
</tr>
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<tbody>
<tr>
<td>Central</td>
<td>3</td>
<td>3</td>
<td>6</td>
<td>6</td>
<td>12</td>
<td>3</td>
</tr>
<tr>
<td>Regional</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>5</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>District</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>3</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>SDP</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>0.5</td>
</tr>
<tr>
<td>Total</td>
<td>16</td>
<td>29</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

[Min. = lead time stock level + safety stock level]  
[Max. = minimum + review period]  
[Emergency Order 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, and, 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.

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

ARV drugs and HIV tests both have unique characteristics that often 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, at a minimum, special handling within an integrated or other combined supply chain. Special characteristics of ARV drugs and HIV tests include—

- short shelf life, which can range from six to 24 months
- high price, including a significant jump in price when moving from first line to second line treatment regimens
- high value in prolonging survival for AIDS patients
- treatment and testing protocols that require multiple products from multiple sources to be available simultaneously to provide a service
- limited possibility of substitution in the case of stockouts
- high risk of drug resistance in the case of stockouts.

Due to these unique characteristics, it may not be possible to integrate them 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 any case, the characteristics of ARV drugs and HIV tests require additional system resources over and above those required for a typical supply chain as noted above.

Inventory control system requirements for ARV drugs and HIV tests include—

- shortest possible pipeline
- lower buffer stocks than other health commodities
- more frequent reporting period and order interval.

In view of the logistics system design elements and the key considerations already discussed, DELIVER 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 for ARV drug and HIV test inventory control system design and implementation will achieve pipeline efficiency while addressing the special commodity management requirements of ARV drugs and HIV tests.

1. REDUCE THE LENGTH OF THE SUPPLY PIPELINE.

If ARVs or HIV tests must be managed within an existing supply chain/pipeline, reduce the length of the supply pipeline. If ARVs or HIV tests are to be managed through their own vertical pipeline(s), design the pipeline(s) to be as short as possible.

From the illustrative pipeline seen 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.

In addition, in countries where the number of ART and HIV testing sites is limited, if ARVs or HIV tests are moved through an existing pipeline, regions and/or districts would be required to stock products that are distributed to only a few sites in that region or district.

Strategies for reducing the overall length of the supply pipeline are listed below. It must be noted that strategies to reduce the pipeline 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 an one element is not strong enough to perform under the new requirement.

- **Eliminate an entire level or levels from the supply chain.** This is the single most effective and most common strategy for reducing pipeline length. Intermediate levels such as regional and/or district levels are usually eliminated, and commodities move directly from the central level to the service delivery points. From the example 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. While this results in storage and distribution savings at these levels, it does require more resources for transportation at the central level. However, as the number of ART or HIV testing sites is generally limited, the additional central-level resources required for distribution are usually fewer than those required to maintain secure storage and distribution for ARVs or HIV tests at all intermediate storage facilities.

- **Shorten the order interval at one or more levels.** While 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 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.

- **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.

BUILDING BLOCKS FOR INVENTORY MANAGEMENT OF HIV TESTS AND ARV DRUGS
• **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 and both minimum and maximum stock levels can be reduced.

2. **USE THE FORCED ORDERING VERSION OF THE MAX-MIN INVENTORY CONTROL SYSTEM.**

In light of the special requirements for ARV drugs and HIV tests, and to take advantage of some of the common characteristics of ART and HIV testing programs, the forced ordering version of max-min inventory control system has several key benefits, including—

- The range/number of commodities is relatively limited/low, so all commodities can be ordered at each reporting period.
- 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.
- Reorders are standardized and limited to a regular cycle, reducing some of the burden on transportation. (This system entails less frequent orders and deliveries than does a continuous review system.)
- This version requires less safety stock than the standard version.
- The simple ordering decision rule makes it easier to implement.

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 is the best inventory control system for ARV and HIV test distribution. While the delivery truck variation of forced ordering max-min does put pressure on distribution planning and transport management, it has benefits in addition to those of the forced ordering system noted above. These include—

- 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 logistics duties: data collection, resupply, etc., are done by the delivery team.
- Centralizes transport needs: dedicated vehicles assure 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.
3. **IMPLEMENT A MONTHLY REPORTING PERIOD AND ORDER CYCLE.**

A monthly order cycle limits the amount of buffer or safety stock that facilities need to hold. If ordering and reporting are linked, a monthly order ensures that program managers receive data frequently, which is especially important when expanding services. Monthly ordering and reporting allows program managers to monitor the quantities and range of products being used more frequently. Because logistics data can indicate changes in treatment regimen, timely availability of this data will allow program managers and national-level commodity managers to respond to changes in product requirements and adjust procurements.

It is important to note that, for a monthly reporting period to operate effectively, the lead time for filling an order must be less than one month.

If a monthly ordering and reporting cycle is not possible, the next shortest cycle should be implemented. If a quarterly or greater reporting period and order cycle must be used, then it should be limited to the upper levels or, in any case, to as few levels as possible.

4. **IN A NEW PROGRAM, PHASE IN THE INVENTORY CONTROL SYSTEM FOR SECOND LINE DRUGS AT FACILITIES.**

Starting patients on ART is never an emergency, and switching patients from a first line to a second line treatment due to failure is not widely seen as a clinical emergency. Given that second line drugs generally are significantly more expensive than first line drugs, and that in new programs demand for these drugs is slow, managing second line drugs slightly differently from first line drugs can help a program reduce costs and waste. Rather than stocking all facilities with supplies of second line drugs, these products can be stored centrally until a facility requires them and then provided only to those sites with patients on second line drugs. After the drugs become a regularly managed product at the facility, they can be managed alongside first line drugs at the facilities that require them.

5. **IMPLEMENT A MECHANISM FOR RETURNING PRODUCTS FOR RAPID REDISTRIBUTION BEFORE EXPIRY.**

Despite strict adherence to stock management procedures, a facility may, at some point, find itself overstocked with ARV drugs. Overstocks may be due to any number of reasons, including slower than expected uptake of new patients, higher or lower than anticipated shifts in treatment regimens, or higher than expected rates of treatment abandonment.

In a system with monthly reordering (two-month maximum stock level), if a facility has more than two months of supply, then the overstock should be returned to the supplier so those products can be redistributed and used before they expire. For systems with different maximum stock levels, drugs would have to be returned to the supplier early enough to ensure that they can be reissued and used by the patient before expiry.

A special transaction record should be used to facilitate and track the return of ARV drugs and HIV tests from a lower-level facility to a higher-level facility. This record will identify the products being returned and provide proof of return by the lower-level facility and proof of receipt by the higher-level facility. See the illustrative form *Report for Returning Products* in the annex.
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 is 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.

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 in the and to make long-term procurement and program management decisions. The need for timely and accurate commodity data increases when there is a rapidly expanding program, as is the case for HIV/AIDS programs, where demand for services and client uptake is highly unpredictable.

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 enables 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 if he or she needs to make an emergency order. At the end of the order interval, the product manager will compare current stocks to maximum stock level and place an order for the appropriate 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 determine exceptionally high levels of product expiry, and then initiate action to prevent this situation from happening in the future.
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/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, be processed, and be 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.

![Decision-making process diagram]

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

- **Dispensed to user** are the data on 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). In some systems or for some product categories, issues data are used instead of dispensed-to-user data. Issues data refers to quantities of products that are sent from upper-level facilities to lower-level facilities.

- **Stock on hand** are the data on the usable quantities of stock held at a facility.

- **Losses and adjustments** are the data on 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.

Other data may be included in an LMIS; however, an LMIS must not be so extensive that it becomes a burden on the health care personnel who implement the system or who try to collect data that are not immediately relevant for logistics management decision making. An LMIS must collect only data that will be used for decision making. Data collection forms and reports must be used to collect and transmit the data; it must also be easy to use.

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

- 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 account for 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 are typically used to collect data at the points at which the commodities are managed. These records, which correspond to the three essential data items, include—

- **Consumption** records that capture data about the products being used or dispensed (usage logs or dispensing registers).
- **Stockkeeping** 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 represent 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, is 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 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 ordering 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.

Assuming that ARV drug or HIV test pipelines are shorter than the pipelines used for moving other kinds of commodities, as was recommended in the earlier Inventory Control System, the amount of data aggregation will be reduced. This will also 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.

AVAILABILITY OF DISAGGREGATED DATA
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, because this data are needed for their decision making. For instance, it might be useful for ART or VCT/PMTCT 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 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 service delivery point (SDP).

Refer to *The Logistics Handbook* for more a complete description and additional discussion of logistics management information systems.
SPECIAL 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 due to 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 death, treatment failure, and development of drug resistance. Like 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 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 provide clients with reliable test results.

ISSUES OF PARTICULAR CONCERN IN ARV DRUG AND HIV TEST MANAGEMENT, ALL REQUIRING ACCURATE AND TIMELY INFORMATION
• need for simultaneous and uninterruptable availability at service delivery points of multiple products with different shelf lives from different suppliers to provide quality ART and HIV testing services
• higher levels of accountability, including special reporting or other documentation requirements from either donors or manufacturers
• greater potential for redistribution of products from one facility to another.

ISSUES OF PARTICULAR CONCERN IN ARV DRUG MANAGEMENT, ALL REQUIRING ACCURATE AND TIMELY INFORMATION
• continued uninterrupted resupply for patients already on antiretroviral therapy (ART)
• special ordering and information requirements for second line and alternate drug treatments, if these drugs are not kept routinely at the service site.
ISSUES OF PARTICULAR CONCERN IN HIV TEST MANAGEMENT, ALL REQUIRING ACCURATE AND TIMELY INFORMATION:

• ensured supply of all tests and test-related consumable supplies for testing protocols

• kit contents and packaging considerations (e.g., number of tests per kit, inclusion of chase buffer, different expiration dates for tests and buffer)

• testing protocols (serial and parallel testing).

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 a vertical system for managing HIV tests, would require its own vertical LMIS.

At the program management level, for program planning, quantification, and procurement planning, often additional, nonessential logistics information may be needed for effective decision making. This additional information cannot be compiled from logistics data, but must come, instead, from patient and program data that should be collected routinely through the health management information system (HMIS) established for the HIV/AIDS program. Ideally, logistics managers should have access to information available through the HMIS to facilitate program planning and routine supervision. However, 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 or weight gain (calculated data)

• rates of patients switching regimens (calculated data)

• changes in pediatric regimen due to weight gain, intolerance, toxicity, or treatment failure

• 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 or PMTCT services and are tested

• number of tests used, by purposes of use, brand, and use of test

• accounting for test-related supplies.
RECOMMENDATIONS FOR ARV DRUG AND HIV TEST LOGISTICS MANAGEMENT INFORMATION SYSTEM DESIGN AND IMPLEMENTATION

1. LINK ROUTINE REPORTING TO COMMODITY ORDERING
There are many benefits to linking routine reports to commodity orders. For example, a system with monthly reporting and monthly ordering has inherent advantages over a system with monthly reporting and quarterly ordering. Often, commodity managers may ignore reporting that does not produce a tangible benefit or result, which is in this case, receiving commodities that result from an order linked to a report. Other advantages to linking reporting and ordering are—

- 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.

While some might argue that “no report, no commodities” would penalize nonreporting facilities, it is crucial to remember that the data contained 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 proven to be an acceptable solution. However, policymakers or relevant authorities should always be involved in approving this decision.

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

2. AVOID OVERBURDENING THE LMIS BY COLLECTING SERVICE STATISTICS OR OTHER DATA THAT DO NOT HAVE A DIRECT BENEFIT TO MANAGING COMMODITIES.
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/AIDS program managers. These types of data can ultimately help in making logistics-related decisions, such as forecasting. Reporting formats should not collect any data that do not benefit commodities management.

3. ALWAYS COLLECT AND REPORT DISPENSED-TO-USER DATA FOR ARVS AND USAGE DATA FOR HIV TESTS; ISSUES DATA 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 a therapeutic, safety, and financial perspective impose greater demands for accountability.
4. **REFRAIN FROM ALTERING THE CONTENT AND FORMATTING OF THE LMIS TO ACCOMMODATE THE FUNDING MECHANISM.**

The landscape of supply chain management for ARVs and HIV tests is marked by the presence of multiple donors operating with different agendas, program objectives and goals, and reporting requirements. These often competing agendas may put pressure on the respective LMIS used to manage the products, with the contents or data items included on the LMIS determined by the funding mechanism. However, aside from the few exceptions noted above, the logistics data needed to run a system does not change significantly over time: logistics data are logistics data. However, funding mechanisms constantly change. If an LMIS is designed to respond to the needs of one donor, it will need to change if that donor withdraws support and is replaced by another. Data collected on the LMIS forms should suit the particular program needs and be used for decision making; they should not, however, be dictated by individual donor requirements. If funding mechanism reporting requirements are so specific as to require additional data or information, then those data or that information should be collected and reported separately, not within the LMIS used for commodity management.

5. **QUANTITIES TO ISSUE OF ARV DRUGS AND HIV TESTS SHOULD BE CONVERTED FROM UNITS TO PACKS AT THE ISSUING LEVEL, NOT AT THE ORDERING LEVEL.**

Programs frequently procure drugs from multiple suppliers. Thus, pack sizes of drugs and HIV tests frequently change. Depending on the number of funding and procurement sources that exist in a program, a central warehouse can have multiple brands of the same ARV drug in stock at the same time, some of which may be packaged in different pack sizes. In a pull system, where facilities calculate order quantities and send these to the issuing facilities, it is strongly recommended that the ordering quantities be recorded and submitted as basic units (e.g., tablets, capsules, individual number of tests). This will allow the issuing facilities to convert the units into pack sizes based on what they have in stock and following sound warehouse practices (such as first-to-expire [FEFO]). Also, this is likely to reduce errors that might occur if the issuing facility received orders in inappropriate pack sizes, had to convert them back into units, and then reconvert them into packs based on their existing stocks.

**RECOMMENDATIONS FOR ARV DRUG LOGISTICS MANAGEMENT INFORMATION SYSTEM DESIGN AND IMPLEMENTATION**

1. **IN ADDITION TO THE THREE ESSENTIAL LOGISTICS DATA ITEMS, LIMIT THE AMOUNT OF PATIENT DATA THAT ARE COLLECTED AND REPORTED; AND TRACK THE NUMBER OF NEW AND EXISTING PATIENTS BY TREATMENT REGIMEN. USE THESE DATA FOR DECISION MAKING.**

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. These data may be collected through LMIS reports or other routine HMIS reports. 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.

Patient data may be best collected by ART service providers, rather than by commodity managers. In this case, the service provider and the commodity manager have to work together to complete a single report that contains data from each.

Therefore, it is necessary for the LMIS, which generally focuses exclusively on logistics data, to also collect limited elements of patient data. To correctly determine product resupply quantities, particularly when buffer stocks are not maintained, LMIS reports should include the total number of products needed to treat patients, in addition to dispensed-to-user,
stock on hand, and losses and adjustments data. (See description below and sample forms in the annex.)

For many health commodities, consumption is relatively stable over the short term and may increase or decrease gradually over the long term. In such a situation, the three essential data items noted earlier are sufficient for making commodity management decisions. This would also be the case for an established ART program using a forced ordering max-min system with frequent resupply and sufficient levels of safety stock for all drugs required. For example, with monthly ordering, a two-month maximum stock level should provide enough stock to serve existing and new patients.

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:

\[
\text{Quantity to Order} = (\text{Average Monthly Consumption} \times 3) - \text{Stock on Hand}
\]

In a rapidly expanding program, however, the addition of new patients may exceed the system's capacity to maintain adequate stock levels. For example, if a program is more than tripling the number of patients on ART each month, then a three-month max calculated using average monthly consumption over the past three to six months would not be enough to maintain product quantities for new patients. One strategy is simply to increase the maximum and minimum stock levels (add an additional two or three months of additional buffer against uncertainty). This may be a difficult solution in some countries because of the high additional cost this would entail. Another strategy—considering the patient data—combines logistics data with patient data to determine reorder requirements. In this case, patient-related data, specifically the estimated number of new patients by treatment regimen for the next month, is required. After the estimated number of new patients is known, then the drug requirements for those new patients can be determined and added to existing dispensed-to-user logistics data for calculating order quantities.

Using patient data combined with logistics data, and assuming monthly reordering with a three-month maximum stock level (one month dispensing stock, one month lead time stock and one month safety stock), order quantities would be determined using the following formula:

\[
\text{Quantity to Order} = (\text{Consumption} \times 3) + (\text{Quantity required for new patients} \times 3) - \text{Stock on Hand}
\]

In a situation when a program cannot fund normal levels of safety stock, then the minimum (and maximum) stock levels must be reduced. For example, a program may decide to use a two-month maximum instead of three months. This would provide enough stock for one month of consumption, three weeks of lead time stock, and a one-week safety stock. Using patient data combined with logistics data, order quantities would be determined using the following formula:

\[
\text{Quantity to Order} = (\text{Consumption} \times 2) + (\text{Quantity required for new patients} \times 2) - \text{Stock on Hand}
\]
Note: In this example, with a two-month maximum (one month of dispensing stock + one month of lead time and safety stock); lead time must be three weeks or less. This example is referenced in the sample LMIS forms in the annex.

It should be noted that the combined use of logistics data and patient data results in a much more complicated set of calculations to determine resupply quantities. If patient data is being used to project reorder quantities, then it is strongly recommended that a computerized system be used to make those calculations. Further, if a computerized system is being used, then it is likely to be used more effectively in a pull system situation.

2. IF PROGRAM REPORTING CAPTURES ESTIMATES OF NEW PATIENTS, PROVIDE WORKSHEETS TO TRANSLATE PATIENT NUMBERS INTO PRODUCT NUMBERS.

In addition to the three types of logistics records mentioned earlier, an LMIS for ARVs might include a register or other record specifically designed to collect patient information, such as number of patients per treatment regimen, that will provide the additional patient information required to manage ARV drugs.

Logistics data collected through an LMIS for ARV drugs come from basic logistics records, such as stockcards and dispensing logs. The information from those sources reflects only past consumption/product use. To estimate future quantities of products needed, during the next order cycle, for instance, facility staff will need to translate the number of patients who will be served into the quantities of products that will be needed to serve those patients. For this purpose, it is suggested that a worksheet be developed and implemented that guides service personnel in calculating those product quantities. The worksheet would include the number of new patients by treatment regimen and a mechanism for determining the number of drugs required for each regimen and for calculating the total quantity of each drug needed for all expected new patients. This information would then be transferred to the report and order form. (See the annex for a sample worksheet, Worksheet for Calculating Monthly ARV Drug Orders for Estimated New ART Patients.)

In addition to being a useful tool for ordering, the worksheet can be used for monitoring and supervision. Periodically, program managers can use the worksheet to monitor ARV drug use by cross-checking and comparing the number of patients being served and the quantities of products being requested. Because some drugs are used in multiple regimens, the worksheet could also aid program managers in monitoring prescribing and dispensing protocols.

3. SELECT AND CONSISTENTLY USE ONE UNIT FOR RECORDING DRUGS.

As with all drugs and other medical supplies, data collected on LMIS records (dispensing registers, stockcards, etc.) 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.

However, standard logistics practice uses the smallest possible unit (tablet, capsule, ml, etc.), and the program should seriously consider following that practice, given that bottle quantities vary by supplier and can change over time. This is particularly important when tracking of paediatric solu-
tions. For example, nevirapine oral suspension is available in 20 ml, 100 ml, and 200 ml bottle sizes. If all bottle sizes are stocked at the central warehouse and supplied based on what is in stock, and if LMIS reports only capture logistics data by bottle, tracking usage and calculating resupply quantities will be difficult, if not impossible. Tracking liquids using ml as the basic unit will allow resupply calculations to be made accurately, while considering bottle sizes in stock. The important point is that the recording unit is consistent, and that it is known and used by all program personnel.

4. SEPARATE CLINICAL/PROGRAM INFORMATION USED FOR PROGRAM MONITORING FROM LOGISTICS AND PATIENT DATA COLLECTED FOR LOGISTICS DECISIONS.

As discussed earlier, when managing ARV drugs, some patient data are needed to inform resupply and other commodity management decisions. Such data, however, are often not readily available through an HMIS or other information/data-gathering system. Thus, the tendency might be for the burden to fall to the LMIS to collect and report such data regularly and frequently.

It is tempting to use the LMIS to collect other patient or program data; it is simple to add additional data collection columns to the LMIS forms and reports. However, doing so can easily create situations where the logistics data are lost, either by having reports pass through program managers before going to commodity managers or by making the data collection process so cumbersome that the logistics information is no longer collected and reported in a timely way. In any case, there is the risk that collected data are not available or used for resupply, which is the main purpose of the LMIS.

Certainly, it is important to collect and use information on aspects of the ARV program aside from commodity management, such as monitoring patient adherence to their treatment regimens, toxicity rates, rates of first line drug resistance, and so forth. However, a separate system should be used for collecting and using this information. In fact, medical or program personnel should be monitoring these aspects of the program through their own reporting mechanisms not logistics/commodity managers through the LMIS.

RECOMMENDATIONS FOR HIV TEST LOGISTICS MANAGEMENT INFORMATION SYSTEM DESIGN AND IMPLEMENTATION

1. IN ADDITION TO THE THREE ESSENTIAL LOGISTICS DATA ITEMS, LIMIT OTHER DATA COLLECTED AND REPORTED THROUGH THE LMIS; AND TRACK USAGE OF HIV TESTS BY PURPOSE, BRAND, AND USE OF THE TEST.

HIV tests can have multiple purposes of use: for PMTCT, 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. The LMIS for HIV tests may be used to track quantities of HIV tests used by purpose, brand, and use of the test. Capturing these data has significant benefits for program management, especially for monitoring program expansion and forecasting future needs.

The information is also useful from a supply chain management point of view. 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. Also, experience has shown that the information summarized by use of test (i.e., 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 non-standard 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 correct supplies of each brand are issued after the supply situation is corrected.

Logistics data can also be supplemented by a limited amount of patient data. The availability of such data can tend to increase the accountability of the number of HIV tests used. Additionally, such data can contribute to long-term forecasting by showing trends in proportions by purpose, such as VCT, PMTCT, or clinical diagnosis. However, capturing data other than logistics data—for example, the numbers of clients served—is a decision that program managers should make; but the program managers must recognize that limited data should be collected to avoid making the system cumbersome or unwieldy. Data should never be collected if it will not be used for decision making.

See the forms in the annex, _Daily Log for Usage of HIV Tests_ and _LMIS Report and Request for HIV Tests_.

2. **USE THE INDIVIDUAL TEST AS THE UNIT FOR RECORDING.**

Logisticians and program managers must agree on the unit of recording used to manage HIV tests based on kit contents and packaging. It is recommended that the HIV tests be recorded by test, rather than by kit. Also when a site is stocked out of its preferred screening test, it may use another brand temporarily to screen clients until the original brand is resupplied. For example, a facility may use a low number of HIV tests but be unable to use an entire HIV test kit (which may include 100 tests) before the tests expire or the facility stocks out of chase buffer but still has several tests left. The facility does not need an entire test kit, just more chase buffer. In either case, the commodity manager needs specific information on the number of tests, not the number of kits, to take the appropriate action. This is only possible when the unit of tracking is the test, not the kit.

3. **MANAGE TEST-RELATED SUPPLIES THROUGH THE EXISTING SYSTEM FOR LABORATORY SUPPLIES.**

One common challenge regarding test-related supplies is managing reagents and other consumable laboratory supplies, such as lancets, pipettes, blood collection devices, and gloves. Tracking such supplies, which are used 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.

The only exception would be if there is no established supply chain for laboratory consumables. In this case, such products could be included in the LMIS for HIV tests to ensure their availability for HIV testing.

Refer to _The Guidelines for Managing the Laboratory Supply Chain_ for a more complete description.
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 service delivery points 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 a 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.

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.

Acceptable storage facilities (warehouses, storage rooms) are clean and secure, and adequate distribution systems have dependable and secure delivery vehicles. It is desirable for the pipeline to 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 to occur. 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. To ensure that happens, products should be ordered and issued 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 for more a complete description and additional discussion of standard storage guidelines for health commodities.
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 comes to 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 could take precedence over commodity delivery, which could delay the movement of commodities and could 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.

SPECIAL 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 also affect the methods used for storage and distribution of these commodities. These characteristics include—

• short shelf life, ranging from six to 24 months
• high price
• high value in prolonging survival for AIDS patients
• necessity for cool storage
• limited number of sites authorized to use these products
• other commodities needed for administration
• use in specific combinations with other drugs.

In some cases these special characteristics may require implementation of a unique procedure for handling ARV drugs or HIV tests, but in other cases all that is required is a higher level of attention to or emphasis on 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. In addition to storing them in a dry, well-lit, well-ventilated store-room, out of direct sunlight, ARVs should not be opened to repack 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 to 8° Celsius; 36 to 46° Fahrenheit) 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 and used by the client.

An additional consideration for ARV drug and HIV test distribution is the increased pressure on the transportation system, due to—

• lower safety stocks

• more frequent resupply cycle

• deliveries to accredited sites only.

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

I. WHENEVER POSSIBLE, INTEGRATE STORAGE AND DISTRIBUTION OF ARV DRUGS AND HIV TEST KITS.

Integrating the storage and distribution of ARV drugs and HIV tests can help avoid duplication of activities and result in better use of limited resources. However, it is critical to ensure that integrating these products into an existing system also makes sense from overall program and product management concerns. The feasibility of operating a fully integrated system will depend on a number of factors, including—

Management and reporting structure: If a program is charged with managing its own commodities (inventory control system) and reporting structure (LMIS), then it may make more sense to manage the storage and distribution of these products separately as well. This does not necessarily require establishing a completely separate storage facility; it could be accomplished by delineating a specific section of an existing storage facility for ARV drugs and HIV tests.

Number of facilities involved: If the number of facilities providing ART or HIV testing is relatively small compared to the number of facilities in the country, then moving products through an existing system may be counterproductive. For example, intermediary facilities (such as regional or district warehouses) would have to hold stock that would be distributed to very few facilities, lengthening the overall supply pipeline and adding to safety stock requirements.

Available resources: If a program has obtained its own vehicles, then it may make sense to use those vehicles for product distribution, rather than relying on other shared vehicles. This is especially true if ARVs or HIV tests have different ordering intervals from other items stored at a facility.
2. PROVIDE INCREASED LEVELS OF SECURITY DURING STORAGE.
Due to the high value of ARVs and HIV test kits, higher levels of security are required for these commodities. 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/AIDS commodities:* The number of people who are allowed to access the secure storage area should also be limited. However, systems must be in place to ensure that someone with access is always available for filling regular or emergency orders, even if the total number of people with access is limited.

*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 stockkeeping 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 product and the storekeeper.

*More frequent audits:* Facilities that report and order monthly should automatically conduct physical inventory and verify stock-keeping records each month when the report is completed and the order is placed. For facilities that report less frequently, a monthly physical inventory or other audit of HIV/AIDS commodities should be conducted.

3. ENSURE INCREASED SECURITY DURING TRANSPORT.
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 may even be necessary to provide armed guards or other supplemental security measures.

4. PAY SPECIAL ATTENTION TO FIRST-TO-EXPRIE, FIRST-OUT.
Due to the short shelf life and high cost of ARV drugs and HIV tests, special care must be taken to follow first-to-expire, first-out (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.

5. 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 if the product is not close to expiry, it can be reissued to another patient.

6. **DELIVER ARV DRUGS AND HIV TESTS TO ACCREDITED SITES ONLY.**
ARV drugs and HIV tests should be distributed only to sites that are accredited or otherwise authorized for their use. This is easy to control in a vertical system; only authorized sites will be submitting orders for those products. In an integrated system, however, an extra level of control or oversight may be required. This may mean separate order forms for ARV drugs and HIV tests, which are only submitted by accredited facilities, or it may mean an extra signature by program personnel authorizing the order to be filled. Keep in mind, that there should not be so many controls in place—for example, extra signatures—that movement of the commodities is delayed.

7. **CONSIDER USING PRIVATE OR OTHER COURIER/EXPRESS MAIL FACILITIES.**
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 one or more vehicles and the personnel needed 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 those products that require it. The program is responsible for monitoring the performance of the couriers.

8. **ENSURE THAT PRODUCTS USED TOGETHER ARE DISTRIBUTED TOGETHER.**
Some HIV tests come packaged with most, if not all, consumable supplies needed to run the tests. However, several available tests do not come equipped with the necessary supplies. ARV drugs must be used in certain combinations in a specific regimen. If one drug is missing from a regimen, no substitutions can be made, and the patient cannot be treated. In both cases, ideally, all necessary products are ordered to provide the services the customers need. ARV drugs should be ordered together to ensure the proper regimen can be used. It is essential that the entire complement of products ordered is distributed together, at the same time, so that services such as HIV tests and ART can be given immediately upon receipt. If a reliable supply chain already exists for laboratory consumables, including those used with HIV tests, then that supply chain can be used to order and distribute lab supplies. It is then the job of the service provider to ensure that all necessary supplies are available where and when services are provided.

In Kenya, the National AIDS program has a contract with a local courier service to deliver ARVs on an emergency basis and to receive and forward monthly reports and orders to the national program. The arrangement has worked well and has resulted in greater than 90 percent reporting rates for LMIS reports for ARV drugs, although resources have been dedicated for ongoing monitoring of invoices and other required paperwork.
REFERENCES


REFERENCES


ANNEXES

1. CASE STUDY
2. SAMPLE LMIS RECORDS AND REPORTS
3. JOB AIDS
This case study describes the supply chains for ARV drugs and HIV tests for the HIV/AIDS program in the imaginary country of Kaamanland, and it provides a context in which to review the records and reports that follow.

While Kaamanland is imaginary, the supply pipeline, inventory control system, and logistics management information system (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, antiretroviral therapy (ART) is currently provided in 14 ART sites—the national teaching hospital and regional hospitals. Within the next year, ART services will be expanded and available through accredited district hospitals. At that point, ART will be available at 60 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 forced ordering maximum-minimum. 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 ART Daily Activity Register to record the quantity of each drug given to patients in the dispensing area. Stockcards are used to record stocks received and issued, losses and adjustments, and stock on hand for ARV drugs stored at the service site. At the end of each month, the ART service provider together with the therapeutic committee look at their existing ART patient profile and determine the number of new patients who will be starting ART the following month. They record this information on the Monthly Summary Report of ART Patients and use the new patient information from that report to complete the Worksheet for Calculating Monthly ARV Drug Orders for Estimated New Adult ART Patients, which calculates the quantity of each ARV drug needed for the new patients for the next month.

The ART service provider uses the records, report, and worksheet to complete the LMIS Report and Request for Antiretroviral Drugs. The report and request is sent to the data-processing center 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, and reports on ART sites and central warehouse activities 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.

If an ART site has overstocks of any ARV drug, these drugs may be returned for redistribution to the central medical stores at the time the driver makes a routine delivery. The ART service provider and the driver use the Report for Returning Products to document the transfer of drugs.

In addition to the monthly report and request, each ART site prepares and submits the Monthly Summary Report of ART Patients to the data processing center. Program management uses this information to monitor ART services.

**Kaamanland HIV Test Program and Supply Chain**

In Kaamanland, HIV testing is conducted in a variety of settings, including voluntary counseling and testing (VCT) centers; clinics offering prevention of mother-to-child transmission (PMTCT); and national, regional, and district hospitals.

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 delivery truck, forced ordering maximum-minimum. 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 VCT, PMTCT, and clinical diagnosis.

Stockcards 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 records and daily logs 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 data-processing center of the Ministry of Health, where the information is compiled. Information processed from the reports, along with reports of stock levels in the National Reference Laboratory, is sent 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.
Kaamanland
ARV Drug Pipeline

Program Management

Quarterly Revised Quantification

External Supplier

Central Medical Stores

Quarterly shipments from external supplier:
- 3 months minimum stock
- 6 months maximum stock

LMIS forms at CMS:
- Stockcards
- Transaction records

Data Processing Center

Monthly reports from CMS:
- Stock position
- Deliveries and issues

Monthly reports from processing center:
- National stock position
- Pipeline analysis
- Delivery performance
- Reporting rate

Monthly reports from SDPs:
- LMIS Report and Request for ARV Drugs
- Monthly Summary Report of ART Patients

Monthly orders for facilities

ART Service Delivery Point

Inventory system:
Forced ordering max-min:
- 1 month minimum stock
- 2 months maximum stock

LMIS forms at SDP:
- ART Daily Activity Registers
- Monthly Summary Report of ART Patients
- Worksheet for Calculating ARV Drug Quantities
- LMIS Report and Request for ARV Drugs
- Report for Returning Products
- Program Form at SDP

ART Patients

Flow of drugs

Flow of information

Flow of drugs

Flow of information

Program Management

Central Medical Stores

Data Processing Center

ART Patients

External Supplier

ANNEX 35
Figure 2

**Kaamanland**

**HIV Test Pipeline**

- **Program Management**
- **Data Processing Center**
- **External Supplier**
- **National Reference Laboratory**
- **HIV Testing Sites**
  - VCT Centers
  - PMTCT Clinics
  - National, Regional, and District Hospital Laboratories

Flow of drugs: """
Flow of information: ""

**Monthly reports from processing center:**
- National stock position
- Pipeline analysis
- Delivery performance
- Reporting rate

**Copies of LMIS Report and Request for HIV Tests**

**Quarterly Revised Quantification**

**Quarterly shipments from external supplier:**
- 3 months minimum stock
- 6 months maximum stock

**LMIS forms at NRL:**
- Stockcards
- Transaction records

**Monthly resupply from reference lab delivery team to service point**

**Inventory system:**
Delivery truck, forced ordering max-min:
- 1 months minimum stock
- 2 months maximum stock

**LMIS forms at Testing Site:**
- Daily Log for Usage of HIV Tests
- Stockcards
- LMIS Report and Request for HIV Tests
- Transaction Records

**36 BUILDING BLOCKS FOR INVENTORY MANAGEMENT OF HIV TESTS AND ARV DRUGS**
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 manual. 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 only include 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 (i.e., maximum stock levels, treatment protocols/testing algorithms, etc.). Nevertheless, the sample forms do reflect the recommendations and guidelines indicated throughout this manual. Furthermore, the preprinting of commodity names, units, etc., 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 that are critical for an effective LMIS and country programs, include stock-keeping records (e.g., stock cards, bin cards, etc.) that track information on commodities in the storeroom; and transaction records (e.g., issue vouchers, packing slips, etc.) that track movement of commodities between different levels in the system.

ART Daily Activity Register: This consumption record is used to track ARV drugs; it is maintained by the service providers who dispense drugs to patients. The quantities generated feed into the monthly consumption totals and are used to determine average monthly consumption and reorder quantities.

Monthly Summary Report of ART Patients: This program report is used to report the number of patients on ART by treatment regimen. It provides data on current and estimated number of new patients by regimen, which is useful for routine ordering during rapid scale-up.

Worksheet for Calculating Monthly ARV Drug Orders for Estimated New Adult ART Patients: This worksheet is used to translate the estimated number of new patients into the quantities of ARV drugs that will be required to treat the patients. The pharmacist or person responsible for ordering should complete the forms. Because pediatric dosing is non-standard, this worksheet is only applicable for estimating drug orders for adults. WHO is currently developing a web-based tool to facilitate calculations of pediatric dosages, and as DELIVER gains more experience, they will update their guidelines with useful tools for calculating pediatric orders.

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 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.

**Record for Returning Products:** This transaction record is used to track products (ARV drugs and HIV tests) that are returned to the supplier for redistribution or, in the case of expired drugs, for destruction. While a generic issue and receipt voucher could also be used, the specific “Report for Returning Products” includes reasons for returning products that could be important in monitoring the logistics system, service provision, and the overall program.
Interrelationships between LMIS Records and Reports for ARV Drugs

- **REPORTS**
  - Monthly Summary Report of ART Patients
  - LMIS Report and Request for Antiretroviral Drugs
  - Report for Returning Products

- **RECORDS**
  - Worksheet for Calculating Monthly ARV Drug Orders for Estimated New Adult Patients
  - ART Patient Records/Register
  - ART Daily Activity Register
  - Stock Card/Bin Card

- **Data**
  - Total quantities of each drug dispensed during the reporting period
  - Opening Balance Losses and Adjustments
  - Quantity Received
  - Closing Balance
  - Adjustments
Interrelationships between LMIS Records and Reports for HIV Tests

- **Data**
  - REPORTS
  - RECORDS

- **LMIS Report and Request for HIV Tests**
  - Total quantities of tests used for the reporting period by purpose of use, brand, and use of test

- **Report for Returning Products**
  - Opening Balance
  - Losses and Adjustments
  - Quantity Received
  - Closing Balance

- **Daily Log for Usage of HIV Tests**

- **Stock Card/Bin Card**
## ART DAILY ACTIVITY REGISTER

### Facility: _____________

<table>
<thead>
<tr>
<th>District: _____________</th>
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### Date | Patient Name/Number |  |  |  |  |  |  |  |  |  |
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### Quantities Dispensed

<table>
<thead>
<tr>
<th>Fixed Dose Combinations</th>
<th>Single Drug Formulations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stavudine/Lamivudine/Nevirapine</strong></td>
<td><strong>Effavirenz</strong></td>
</tr>
<tr>
<td>30/150/200 mg Tabs</td>
<td>600 mg Tabs</td>
</tr>
<tr>
<td>40/150/200 mg Tabs</td>
<td>200 mg Caps</td>
</tr>
<tr>
<td><strong>Stavudine/Lamivudine</strong></td>
<td><strong>Lamivudine</strong></td>
</tr>
<tr>
<td>30/150 mg Tabs</td>
<td>50 mg Tabs</td>
</tr>
<tr>
<td>40/150 mg Tabs</td>
<td><strong>Nevirapine</strong></td>
</tr>
<tr>
<td><strong>Zidovudine/Lamivudine</strong></td>
<td>300/150 mg Tabs</td>
</tr>
<tr>
<td><strong>Zidovudine</strong></td>
<td><strong>Stavudine</strong></td>
</tr>
<tr>
<td>30 mg Tabs</td>
<td>40 mg Tabs</td>
</tr>
<tr>
<td><strong>Abacavir</strong></td>
<td><strong>Didanosine</strong></td>
</tr>
<tr>
<td>300 mg Tabs</td>
<td>250 mg Caps</td>
</tr>
<tr>
<td>400 mg Caps</td>
<td><strong>Nelfinavir</strong></td>
</tr>
<tr>
<td><strong>Zidovudine syrup</strong></td>
<td>10 mg/ml</td>
</tr>
<tr>
<td><strong>Lamivudine oral solution</strong></td>
<td>10 mg/ml</td>
</tr>
<tr>
<td><strong>Nevirapine oral suspension</strong></td>
<td>10 mg/ml</td>
</tr>
<tr>
<td><strong>Stavudine oral solution</strong></td>
<td>10 mg/ml</td>
</tr>
<tr>
<td><strong>Abacavir oral solution</strong></td>
<td>20 mg/ml</td>
</tr>
<tr>
<td><strong>Didanosine powder for oral suspension</strong></td>
<td>10 mg/ml</td>
</tr>
<tr>
<td><strong>Nelfinavir powder for oral suspension</strong></td>
<td>50 mg/g</td>
</tr>
</tbody>
</table>

### Total Quantity Dispensed:

### Quantity Dispensed for Month (running total):
**MONTHLY SUMMARY REPORT OF ART PATIENTS**

Reporting Period: From __________ to ______________

Facility: ____________________________ District: __________________________________

<table>
<thead>
<tr>
<th>Code</th>
<th>Regimens</th>
<th>Current No. Patients This Month</th>
<th>Estimated No. New Patients Next Month</th>
<th>Total No. of Patients Next Month</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A</strong></td>
<td>ADULT First Line</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A1</td>
<td>Zidovudine 300 mg + Lamivudine 150 mg + Nevirapine 200 mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A2</td>
<td>Zidovudine 300 mg + Lamivudine 150 mg + Efavirenz 600 mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A3</td>
<td>Stavudine 30 mg + Lamivudine 150 mg + Nevirapine 200 mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A4</td>
<td>Stavudine 40 mg + Lamivudine 150 mg + Nevirapine 200 mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A5</td>
<td>Stavudine 30 mg + Lamivudine 150 mg + Efavirenz 600 mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A6</td>
<td>Stavudine 40 mg + Lamivudine 150 mg + Efavirenz 600 mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>B</strong></td>
<td>ADULT Second Line</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B1</td>
<td>Abacavir 300 mg + Didanosine 250 mg + Nelfinavir 250 mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B2</td>
<td>Abacavir 300 mg + Didanosine 400 mg + Nelfinavir 250 mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>C</strong></td>
<td>PEDIATRIC First Line</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C1</td>
<td>Zidovudine 10 mg/ml + Lamivudine 10 mg/ml + Nevirapine 10 mg/ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C2</td>
<td>Stavudine 1 mg/ml + Lamivudine 10 mg/ml + Nevirapine 10 mg/ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>D</strong></td>
<td>PEDIATRIC Second Line</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D1</td>
<td>Abacavir 20 mg/ml + Didanosine 10 mg/ml + Nelfinavir 10 mg/ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D2</td>
<td>Abacavir 20 mg/ml + Didanosine 10 mg/ml + Lopinavir/Ritonavir 80 mg/20 mg/ml</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Report prepared by:**

Name: ____________________________ Designation: ____________________________

Signature: ____________________________

---

42 BUILDING BLOCKS FOR INVENTORY MANAGEMENT OF HIV TESTS AND ARV DRUGS
<table>
<thead>
<tr>
<th>Total No. Estimated New Patients by Regimen</th>
<th>Formulations</th>
<th>No. New Patients by Formulation</th>
<th>Fixed Dose Combinations (FDC)</th>
<th>Single Drug Formulations (SDF)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Stavudine/Lamivudine/Nevirapine 30/150/200 mg Tabs</td>
<td>Stavudine/Lamivudine/Nevirapine 40/150/200 mg Tabs</td>
<td>Efavirenz 600 mg Tabs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stavudine/Lamivudine/Nevirapine 30/150 mg Tabs</td>
<td>Stavudine/Lamivudine/Nevirapine 40/150 mg Tabs</td>
<td>Efavirenz 200 mg Caps</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stavudine/Lamivudine 30/150 mg Tabs</td>
<td>Stavudine/Lamivudine 40/150 mg Tabs</td>
<td>Nevirapine 200 mg Caps</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Zidovudine/Lamivudine 300/150 mg Tabs</td>
<td>Zidovudine 300 mg Caps</td>
<td>Stavudine 30 mg Tabs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Zidovudine/Lamivudine 300/150 mg Tabs</td>
<td>Zidovudine 40 mg Tabs</td>
<td>Lamivudine 150 mg Tabs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Zidovudine 300 mg Caps</td>
<td>Zidovudine 400 mg Caps</td>
<td>Abacavir 300 mg Tabs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Didanosine 250 mg Caps</td>
<td>Didanosine 400 mg Caps</td>
<td>Nelfinavir 250 mg tabs</td>
</tr>
</tbody>
</table>

**Adult First Line Regimens**

- **Stavudine 30 mg + Lamivudine 150 mg + Nevirapine 200 mg**
  - FDC
  - FDC + SDF
  - SDF

- **Stavudine 40 mg + Lamivudine 150 mg + Nevirapine 200 mg**
  - FDC
  - FDC + SDF
  - SDF

- **Stavudine 30 mg + Lamivudine 150 mg + Efavirenz 600 mg**
  - FDC + SDF
  - SDF

- **Stavudine 40 mg + Lamivudine 150 mg + Efavirenz 600 mg**
  - FDC + SDF
  - SDF

- **Zidovudine 300 mg + Lamivudine 150 mg + Nevirapine 200 mg**
  - FDC + SDF
  - SDF

- **Zidovudine 300 mg + Lamivudine 150 mg + Efavirenz 600 mg**
  - FDC + SDF
  - SDF

**Adult Second Line Regimens**

- **Abacavir 300 mg + Didanosine 250 mg + Nelfinavir 250 mg**
  - SDF

- **Abacavir 300 mg + Didanosine 400 mg + Nelfinavir 250 mg**
  - SDF

**Total no. new patients per drug (A)**

<table>
<thead>
<tr>
<th>N. pills/patient/30 days (B)</th>
<th>60</th>
<th>60</th>
<th>60</th>
<th>60</th>
<th>60</th>
<th>30</th>
<th>90</th>
<th>60</th>
<th>60</th>
<th>60</th>
<th>60</th>
<th>60</th>
<th>30</th>
<th>30</th>
<th>300</th>
</tr>
</thead>
</table>

**Total Quantity by Drug for 30 days (C)**

(C = A × B)
### LMIS REPORT AND REQUEST FOR ANTIRETROVIRAL DRUGS

**Reporting Period:** From __________ to ______________

**Facility:** ________________________________________

**District:** __________________________

**Maximum Stock Level:** 2 Months

**Minimum Stock Level:** 1 Month

---

<table>
<thead>
<tr>
<th>Product</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Quantity</strong></td>
</tr>
<tr>
<td><strong>Required</strong></td>
</tr>
<tr>
<td><strong>Total</strong></td>
</tr>
<tr>
<td><strong>Maximum</strong></td>
</tr>
<tr>
<td><strong>Opening Balance</strong></td>
</tr>
<tr>
<td><strong>Closing Balance</strong></td>
</tr>
<tr>
<td><strong>Adjusted Quantity</strong></td>
</tr>
<tr>
<td><strong>Dispensed</strong></td>
</tr>
<tr>
<td><strong>Consumption</strong></td>
</tr>
<tr>
<td><strong>Needed</strong></td>
</tr>
</tbody>
</table>

#### Fixed Dose Combinations

- **Stavudine/Lamivudine/Nevirapine 30/150/200 mg**
  - Tab

- **Stavudine/Lamivudine/Nevirapine 40/150/200 mg**
  - Tab

- **Stavudine/Lamivudine 30/150 mg**
  - Tab

- **Stavudine/Lamivudine 40/150 mg**
  - Tab

- **Zidovudine/Lamivudine 300/150 mg**
  - Tab

#### Single Drug Formulations

- **Efavirenz 600 mg**
  - Tab

- **Efavirenz 200 mg**
  - Cap

- **Nevirapine 200 mg**
  - Tab

- **Zidovudine 300 mg**
  - Cap

- **Stavudine 30 mg**
  - Tab

- **Stavudine 40 mg**
  - Tab

- **Lamivudine 150 mg**
  - Tab

- **Zidovudine syrup 10 mg/ml**
  - ml

- **Lamivudine oral solution 10 mg/ml**
  - ml

- **Nevirapine oral suspension 10 mg/ml**
  - ml

- **Stavudine oral solution 1 mg/ml**
  - ml

---

**Prepared by:** __________________________

**Signature:** __________________________

**Date:** __________________________

**Remarks and explanation of losses and adjustments:**
**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: ______________________

<table>
<thead>
<tr>
<th>Date</th>
<th>Client Name/Number</th>
<th>Determine</th>
<th>Uni-Gold</th>
<th>Bionor</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>S C T</td>
<td>S C T</td>
<td>S C T</td>
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</tr>
</tbody>
</table>

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:**

<table>
<thead>
<tr>
<th>Use of Test</th>
<th>Total</th>
<th>Total for the Month (running total)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Confirmatory:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tie breaker:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Legend**

- **S** = Screening
- **C** = Confirmatory
- **T** = Tie breaker
### LMIS REPORT AND REQUEST FOR HIV TESTS

**Reporting Period:** From _____________________ to _________________  
**Facility:** ____________________________________  
**District:** __________________________  
**Minimum Stock Level:** 1  Months

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

### Remarks and explanations of losses/adjustments:

### Summary of Usage of HIV Tests by Purpose, Brand, and Use of Test

<table>
<thead>
<tr>
<th></th>
<th>VCT</th>
<th>PMTCT</th>
<th>Clinical Diagnosis</th>
<th>Blood Safety</th>
<th>Other</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Determine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uni-Gold</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bionor</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Screening</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Confirmatory</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Tie breaker</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Prepared by:**

Full Name ___________________________  Signature ___________________________  Designation ___________________________  Date ___________________________
# REPORT FOR RETURNING PRODUCTS

Sent to: ________________________________________________________________  
Facility returning products: _______________________________________________

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Quantity Returned</th>
<th>Expiry Date</th>
<th>Reason for Return</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Name of person returning the products: ___________________________  Date ____________20___

Signature of person returning the products: ______________________________

**Carrier**

I CERTIFY THAT the above quantities for return were received by me except where explained below.

Name of Carrier _____________________________________  Date ____________20___

Carrier’s Signature ______________________________________

Comments: _____________________________________________

**Receiving Facility**

I CERTIFY THAT the above quantities for return were received by me except where explained below.

Receiver’s Name: ___________________________  Date ____________20___

Receiver’s Signature ______________________________________

Comments: _____________________________________________

_________________________________________________________________________
Note: The following job aids are designed to accompany the sample forms provided for managing ARV drugs and HIV tests. For each form, the job aids provide more detail about the task, purpose, responsible person, and timeframe for completion. As with the sample forms, these have been designed to complement the written guidelines and recommendations in the manual; they represent a system with a monthly reporting and ordering frequency and only include a subset of ARV drugs, rather than the comprehensive list of ARV drugs for all regimens. Because the sample forms are modified to meet program-specific requirements or characteristics (i.e., maximum stock levels, treatment protocols/testing algorithms, etc.), the job aids will also require modification.

JOB AID: COMPLETING THE ART DAILY ACTIVITY REGISTER

This job aid will guide you through the process of completing the ART Daily Activity Register (DAR). This record is kept at the dispensing areas where the drugs are dispensed to patients.

The ART DAR tracks the quantities of drugs dispensed to patients. Every time a drug is dispensed, it must be recorded in the appropriate column. The information collected will be incorporated into the LMIS Report and Request for Antiretroviral Drugs. The ART Daily Activity Register is usually kept in a book or ledger.

<table>
<thead>
<tr>
<th>Task:</th>
<th>Completing the ART Daily Activity Register</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completed by:</td>
<td>Person dispensing drugs (i.e. Dispensing Pharmacist, etc.)</td>
</tr>
<tr>
<td>Purpose:</td>
<td>To record and track the number of ARV drugs dispensed to patients</td>
</tr>
<tr>
<td>When to perform:</td>
<td>Each time an ARV drug is dispensed to a patient and when calculating the running total of drugs dispensed for the month</td>
</tr>
<tr>
<td>Materials needed:</td>
<td>A blank ART Daily Activity Register, calculator, and pen</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Steps</th>
<th>Actions</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Select the appropriate action:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>IF</td>
<td>THEN</td>
</tr>
<tr>
<td></td>
<td>Starting a new book or ledger</td>
<td>Continue to step number 2</td>
</tr>
<tr>
<td></td>
<td>Recording when dispensing drug</td>
<td>Skip to step number 3</td>
</tr>
</tbody>
</table>

Steps to take when starting a new book or ledger

| 2. | ART Daily Activity Register Book or Ledger | |
| Cover: | On the cover sheet write the: | |
| a. | Name of the facility | |
| b. | Name of the district | |
| | Continue with step number 3 | |

The book or ledger will contain daily activity registers for a number of days, depending on the size of the book or ledger.
### Steps to take when starting a new page and dispensing drugs

<table>
<thead>
<tr>
<th>Steps</th>
<th>Actions</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.</td>
<td><strong>Facility:</strong> Write the name of your health facility.</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td><strong>Districts:</strong> Write the name of the district where the facility is located.</td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td><strong>Date:</strong> Enter the date the form was prepared.</td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td><strong>Patient Name/Number:</strong> Write the name and/or number assigned to the patient receiving the ARV drugs.</td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td><strong>Fixed Dose Combinations and/or Single Drug Formulations:</strong> For each patient, enter in the appropriate column the quantities of each drug you dispense.</td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td><strong>Select the appropriate action:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>IF</strong></td>
<td><strong>THEN</strong></td>
</tr>
<tr>
<td></td>
<td>THERE ARE NO MORE BLANK LINES ON THIS PAGE FOR MORE PATIENTS</td>
<td>Continue with step 9 and then go to step 3 when starting a new page</td>
</tr>
<tr>
<td></td>
<td>YOU HAVE SEEN YOUR LAST PATIENT FOR THE DAY</td>
<td>Continue with step 9</td>
</tr>
<tr>
<td>9.</td>
<td><strong>Total Quantity Dispensed:</strong> Write the total quantity of each ARV drug dispensed by adding the quantities entered for each patient listed on the page.</td>
<td>Do this addition each time you complete one page. If there are products that have not been dispensed, write “0” in the spaces on the row for “totals.” Do not leave the spaces blank.</td>
</tr>
<tr>
<td>10.</td>
<td><strong>Quantity Dispensed for Month (running total):</strong> After a page is full, use the total quantity dispensed and previous page running total to calculate the total quantities of each product that you have dispensed so far during the month.</td>
<td>At the end of the last day of the month, add the total quantity dispensed for each drug from the current page; add it to the running total from the previous page to calculate the total quantity of each drug dispensed for the entire month. At the beginning of a new month, with the first patient, start the running total at the bottom of each page with “0” for that month. If you have products that have not been dispensed, write “0” in the spaces on the row for “totals.” Do not leave the spaces blank. You will transfer this total quantity to column D of the LMIS Report and Request for Antiretroviral Drugs when reporting and ordering.</td>
</tr>
<tr>
<td>11.</td>
<td><strong>Check your calculations twice.</strong></td>
<td>Be sure that you have not erroneously entered page totals for one drug item with the totals for another drug item. Any error in the quantities dispensed means that you will not order the correct amount.</td>
</tr>
</tbody>
</table>

### The task is complete when—

- The facility and district names are filled in.
- Patient name and numbers and quantities of drugs dispensed to each patient are entered.
- The quantities of drugs recorded on each row of the page are totaled by column to calculate the total quantity dispensed for each drug.
- The total quantity dispensed for each drug is added to the running total quantity dispensed from the previous page to calculate the running total of the quantities dispensed for the month.
- The total quantities of drugs dispensed during the month are transferred to the LMIS Report and Request for Antiretroviral Drugs (at the time of reporting and ordering).
# JOB AID: COMPLETING THE MONTHLY SUMMARY REPORT OF ART PATIENTS

This job aid will guide you through the process of completing the Monthly Summary Report of ART Patients.

The Monthly Summary Report of ART Patients provides the number of patients by regimen. This form can be used for tracking the number of ART patients, for estimating the numbers of new patients for whom you will order drugs (using the Worksheet below), and for monitoring and supervision to cross-check total numbers of patients by regimen with total quantities of drugs dispensed.

### Task
Completing the Monthly Summary Report of ART Patients

### Completed by
ART service provider or person responsible for reporting

### Purpose
To report the number of ART patients (current and new) by regimen

### When to perform
Prior to completing the Worksheet for Calculating Monthly ARV Drug Orders for Estimated New Adult ART Patients

### Materials needed
Blank Summary Report of ART Patients, calculator, and pen

<table>
<thead>
<tr>
<th>Steps</th>
<th>Actions</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Reporting Period: Write the reporting period with day, month, and year.</td>
<td>e.g., 15/03/2006 to 15/04/2006</td>
</tr>
<tr>
<td>2.</td>
<td>Facility Name: Write the name of your facility.</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>District: Write the name of the district where the facility is located.</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Current No. Patients This Period: Write the total number of patients who are currently on the regimen.</td>
<td>You can obtain the number of patients on each regimen from pharmacy records, if they are tracking numbers of patients on each regimen or, more likely, from the ART clinic patient register. Current patients refer to the patients who were active during the reporting period for the report being prepared.</td>
</tr>
<tr>
<td>5.</td>
<td>Estimated No. New Patients Next Period: Write the number of new patients who are estimated to be enrolled on each regimen.</td>
<td>The number of estimated new patients will probably come from the ART clinic and/or the facility head/manager. Likely sources for this data include the therapeutic committee, the ART clinic waiting list, doctors’ records, or other planning documents.</td>
</tr>
<tr>
<td>6.</td>
<td>Total No. of Patients Next Period: Add the patients currently on the regimen and the estimated new patients who will be on the regimen.</td>
<td>Calculations will be done horizontally by row; this total represents all the current and estimated new patients on each regimen.</td>
</tr>
<tr>
<td>7.</td>
<td>Total: After all the cells in the columns are filled in, add the numbers to obtain the total number of current patients, estimated new patients, and the total of all patients.</td>
<td>These calculations will be done vertically to provide Total Current No. Patients this Period (across all regimens), Total Estimated New Patients for the Next Period, and overall Total of all patients for the next period.</td>
</tr>
<tr>
<td>8.</td>
<td>Report prepared by Name/Designation/Signature: Enter the name and designation of the person preparing the report; preparer signs the report.</td>
<td></td>
</tr>
</tbody>
</table>

### The task is complete when—
- The number of current patients, number of estimated new patients, and total number of patients for the next period are filled in for each regimen.
- The total number of current patients for this period, estimated new patients for the next period, and total number of patients for next period are calculated.
- The person preparing the report writes his/her name and designation and signs the report.
**JOB AID: COMPLETING THE WORKSHEET FOR CALCULATING MONTHLY ARV DRUG ORDERS FOR ESTIMATED NEW ADULT ART PATIENTS**

This job aid will guide you through the process of completing the Worksheet for Calculating Monthly ARV Drug Orders for Estimated New Adult ART Patients.

The worksheet helps the pharmacist to estimate the quantities of ARV drugs that will be needed for new patients beginning treatment during the next resupply cycle. This form can also be used to estimate the quantities of ARV drugs that will be needed for continuing patients who are switching to drugs that are not kept at the facility store.

<table>
<thead>
<tr>
<th>Task:</th>
<th>Completing the Worksheet for Calculating Monthly ARV Drug Orders for Estimated New Adult ART Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completed by:</td>
<td>Pharmacist</td>
</tr>
<tr>
<td>Purpose:</td>
<td>To estimate the quantities of ARV drugs that will be needed for new patients who will be using ARVs, as well as the number of current patients on new regimens</td>
</tr>
<tr>
<td>When to perform:</td>
<td>When a patient starts a regimen for the first time</td>
</tr>
<tr>
<td></td>
<td>Prior to completing the LMIS Report and Request for Antiretroviral Drugs</td>
</tr>
<tr>
<td>Materials needed:</td>
<td>Blank Worksheet for Calculating Monthly ARV Drugs Orders for Estimated New Adult ART Patients, calculator, and pen</td>
</tr>
</tbody>
</table>

Note: The worksheet has darkened cells. You cannot write in the darkened cells. Write only in the blank cells.

The worksheet is completed from left to right, starts with the estimated number of new patients for the next month, and uses those numbers to determine the number of tablets of each drug that need to be ordered for these patients.

<table>
<thead>
<tr>
<th>Steps</th>
<th>Actions</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>For each ART Regimen:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td><strong>Total No. of Estimated New Patients by Regimen:</strong> Write the total number of estimated new patients who will be enrolled on each regimen listed.</td>
<td>The total number of estimated new patients by regimen can be obtained from the Monthly Summary Report of ART Patients. For the first column, and for each regimen row, enter the numbers of new patients, not the quantities of drugs. For example, there are 20 estimated new patients that will receive stavudine 30 mg + lamivudine 150 mg + nevirapine 200 mg. If no new patients will be receiving a regimen, write “0” in that box.</td>
</tr>
<tr>
<td>2.</td>
<td><strong>No. of New Patients by Formulation:</strong> Write the number of new patients who will receive each formulation available.</td>
<td>For each regimen, allocate the total number of estimated new patients entered in the first column to one or more of the available formulations listed (FDC, FDC+SDF, or SDF). The pharmacist or person managing and dispensing stock should make this decision; they should take into account existing stocks on hand, as well as the appropriate clinical factors. The total number of patients across all the formulations within a regimen should total the number of estimated new patients for the regimen. For example, based on the 20 estimated new patients above receiving stavudine 30 mg + lamivudine 150 mg + nevirapine 200 mg, 10 will receive the triple FDC, six will receive the double FDC+SDF, and four will receive just SDFs. If no new patients will be receiving a formulation, write “0” in that box.</td>
</tr>
</tbody>
</table>
### Steps | Actions | Notes
---|---|---
3. **Fixed Dose Combinations and/or Single Drug Formulations:** Enter the number of new patients by formulation into all the unshaded boxes in that row to determine the number of patients receiving each formulation of each drug.

Every time a number is identified for new patients receiving a formulation of a regimen, transfer that number to all the unshaded cells in that row. Continue until all unshaded cells in the regimen rows are filled in. This indicates how many new patients will be receiving each of the drug formulations that make up the regimen. To continue the example from above, enter number 10 in the unshaded cell for the triple FDC; enter number 6 in both the unshaded cell for the double FDC and the unshaded cell for the SDF of nevirapine; enter number 4 in all three of the unshaded SDF cells for stavudine, lamivudine, and nevirapine, respectively.

If no new patients will be receiving a drug, write “0” in that box.

### Now for each drug listed in the columns:

4. **Total No. New Patients per Drug:** Write the total number of new patients who will be receiving each drug.

This calculation is done vertically. Total all the unshaded cells in each column for each drug (i.e., the numbers of new patients that will receive each drug).

If no new patients will be receiving a drug, write “0” in that box.

5. **Total Quantity by Drug for 30 days:** Write the total quantity of each drug required to treat all new patients for the month.

Multiply the total number of patients per drug (row A for that column) by the number of pills per patient, per 30 days (row B for that column).

This is the total quantity of each drug that is needed to treat all new patients during the upcoming 30 days.

Be sure to recheck all calculations in the worksheet. Mistakes in the worksheet will lead to mistakes in determining order quantities.

**Note:** Total Quantities of Drugs for New Patients will be transferred to column F of the LMIS Report and Request for Antiretroviral Drugs.

### The task is complete when—

- The total number of patients is recorded for each regimen.
- The number of patients for each regimen is divided by formulation.
- The total number of new patients, per drug, is entered.
- The total quantity of drugs for 30 days is calculated and the information is transferred to the LMIS Report and Request for Antiretroviral Drugs.
**JOB AID: COMPLETING THE LMIS REPORT AND REQUEST FOR ANTIRETROVIRAL DRUGS**

This job aid will guide you through the process of completing the LMIS Report and Request for Antiretroviral Drugs.

<table>
<thead>
<tr>
<th><strong>Task:</strong></th>
<th>Completing the LMIS Report and Request for Antiretroviral Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Completed by:</strong></td>
<td>The designated person at the SDP responsible for filling the report and placing orders</td>
</tr>
<tr>
<td><strong>Purpose:</strong></td>
<td>To provide logistics data to the central level</td>
</tr>
<tr>
<td></td>
<td>To provide a report on the stock status of ARV drugs at the facility</td>
</tr>
<tr>
<td></td>
<td>To order additional supplies of ARV drugs</td>
</tr>
<tr>
<td><strong>When to perform:</strong></td>
<td>At the end of the order interval (every month)</td>
</tr>
<tr>
<td><strong>Materials needed:</strong></td>
<td>A blank LMIS Report and Request for Antiretroviral Drugs, calculator, and pen</td>
</tr>
</tbody>
</table>

**Note:** This form is prepared in quadruplicate (one original and three copies). Use a pen to fill out the top copy; make sure the writing clearly shows through on all the copies.

Also, remember to write “0” in the boxes if no quantity was received or dispensed, and there were no losses or adjustments. Do not leave boxes blank.

<table>
<thead>
<tr>
<th>Steps</th>
<th>Actions</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Reporting Period:</td>
<td>Write the period of reporting with day, month, and year.</td>
<td>e.g., 15/03/2006 to 15/04/2006</td>
</tr>
<tr>
<td>2. Facility:</td>
<td>Write the name of the facility.</td>
<td></td>
</tr>
<tr>
<td>3. District:</td>
<td>Write the name of the district where the facility is located.</td>
<td></td>
</tr>
<tr>
<td>For each Drug:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Opening Balance:</td>
<td>Write the balance on the beginning of the period of reporting.</td>
<td>You can find the Opening Balance on the stock card or in column E/Closing Balance of the previous report.</td>
</tr>
<tr>
<td>5. Quantity Received:</td>
<td>Write the quantity you received during the month covered by the report.</td>
<td>You can find the quantity received on the stock card.</td>
</tr>
<tr>
<td>6. Losses and/or Adjustments:</td>
<td>Write any losses or adjustments that occurred during the month covered by the report.</td>
<td>You can find losses and adjustments on the stock card. Be sure to write a minus (–) sign for a negative adjustment or loss.</td>
</tr>
<tr>
<td>7. Quantity Dispensed:</td>
<td>Write the quantity that was dispensed to patients during the month covered by the report.</td>
<td>You can find the quantity dispensed on the last page of the ART Daily Activity Register for the month. Use the Quantity Dispensed for the Month (running total) for the month covered by the report. Be sure to check the calculations.</td>
</tr>
</tbody>
</table>
| 8. Closing Balance: | Write the total stock on hand at the end of the month covered by the report. | The closing balance is calculated as the beginning balance plus quantity received minus quantity dispensed plus or minus losses or adjustments. Using the column headings on the form, the formula for the calculation is—
\[ E = A + B +/- C - D \]
The closing balance can also be verified by checking the stock card for the closing balance on the last day of the month order covered by the report, or by conducting a physical inventory of quantities in the storeroom. The stock card needs to be up-to-date; it is recommended that you conduct a physical inventory to check the closing balance. |
<p>| 9. Quantity Required for New Patients: | Write the quantity of ARV drugs that will be required for the estimated new ART patients. | The Quantity Required for New Patients is obtained from row C of the Worksheet for Calculating Monthly ARV Drug Orders for Estimated New Adult ART Patients. |</p>
<table>
<thead>
<tr>
<th>Steps</th>
<th>Actions</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.</td>
<td><strong>Total Estimated Consumption:</strong> Write in the total estimated consumption by adding the quantity dispensed during the month and the quantity required for new patients.</td>
<td>This is the estimated quantity to be dispensed next month; the quantity is the total sum of the quantities dispensed for the month covered by the report being prepared (column D of this report) plus the quantities required for estimated new patients.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Using the column headings on the form, the formula for the calculation is— ( G = D + F )</td>
</tr>
<tr>
<td>11.</td>
<td><strong>Maximum Stock Quantity:</strong> Calculate and write the maximum stock quantity.</td>
<td>The maximum stock quantity is calculated by multiplying the quantity estimated to be consumed during the next month by the maximum stock level. In the example on these forms, the maximum stock level is 2 months; the total estimated consumption is multiplied by 2.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remember; although the maximum stock level remains constant at 2 months, the actual maximum quantities change every time there is an order because the quantity expected to be consumed changes every month.</td>
</tr>
<tr>
<td>12.</td>
<td><strong>Quantity Needed:</strong> Calculate and write the quantity of the product that you need to order.</td>
<td>The Quantity Needed is determined by subtracting the closing balance/stock on hand from the maximum quantity. Using the column headings on the form, the formula for the calculation is— ( I = H - E )</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If the calculation is a negative number (example, – 80), you already have enough stock so the order quantity is “0.” Be sure to write “0” as the order quantity; do not leave the box blank.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>It is highly recommended that the Quantity Needed should be calculated in basic units (i.e., tablets); the issuing facility will convert the quantities to the appropriate pack sizes.</td>
</tr>
<tr>
<td>13.</td>
<td><strong>Remarks:</strong> Write additional comments and any explanations related to losses and adjustments.</td>
<td>For example, if you reported losses or adjustments, give a brief description of the loss/adjustment.</td>
</tr>
<tr>
<td>14.</td>
<td><strong>Prepared by:</strong> Enter the name of the person who prepared the form.</td>
<td></td>
</tr>
<tr>
<td>15.</td>
<td><strong>Signature:</strong> Person who prepared the form signs the form.</td>
<td></td>
</tr>
<tr>
<td>16.</td>
<td><strong>Date:</strong> Enter the date the form was prepared.</td>
<td></td>
</tr>
</tbody>
</table>

The task is complete when—

- The opening balances, quantities received, quantities dispensed, and losses or adjustments are filled in for each product.
- The closing balances are correctly calculated, filled in, and checked against the stock cards.
- The quantities of each drug required for new patients are transferred from the Worksheet for Calculating ARV Drug Orders for Estimated New Adult ART Patients.
- The total estimated consumption is calculated.
- The maximum stock quantities are correctly calculated and filled in.
- The quantities needed are correctly calculated and filled in
- The report/request is signed and dated; losses and adjustments are explained.
JOB AID: COMPLETING THE DAILY LOG FOR USAGE OF HIV TESTS

Task: Completing the Daily Log for Usage of HIV Tests

Completed by: All service providers who perform HIV tests and are responsible for reporting

Purpose: To track usage of HIV tests by purpose of use, brand and use of test
       To collect information for the LMIS Report and Request for HIV Tests

When to perform: Each time an HIV test is performed
                  At the end of each day

Materials needed: A blank Daily Log for Usage of HIV Tests, calculator and pen

Note: The form is printed in a book or ledger.

Using the Daily Log will help you prepare your report at the end of the reporting period. Remember, when you place an order, you will need to provide the total number of tests used during the month by purpose of use, brand, and use of test.

<table>
<thead>
<tr>
<th>Steps</th>
<th>Actions</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Select the appropriate action:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>IF</td>
<td>THEN</td>
</tr>
<tr>
<td></td>
<td>Starting a new book or ledger</td>
<td>→ Continue with step number 2</td>
</tr>
<tr>
<td></td>
<td>Recording when conducting a test</td>
<td>→ Skip to step number 3</td>
</tr>
</tbody>
</table>

Steps to take when starting a new book or ledger

2. Daily Log for Usage of HIV Tests Book or Ledger Cover:
   On the cover sheet write the:
   a. Name of the facility
   b. Name of the district
   Continue with step number 3

Steps to take when starting a new page and conducting tests

3. Purpose of Use of HIV Tests: Check a box for the corresponding service provided.
   The form refers to VCT, PMTCT, Blood Safety, etc.
   It is assumed that a separate Daily Log will be used for each different purpose, (i.e., tests performed for VCT will be recorded on a different Daily Log than those performed for Blood Safety, or PMTCT).

4. Facility: Write the name of your health facility.

5. District: Write the name of the district where the facility is located.

6. Date: Enter the date the form was prepared.

7. Client Name/Number: Write the name and/or number assigned to the client to be tested.

8. S, C, T: Place either a tick (✓), check (✓), cross (✗), or 1 (1) in each cell below the brand (Determine, Uni-Gold, Bionor, other) and below the corresponding use of the test (S for screening, C for confirmatory, and T for tie breaker).
   The brands of tests listed here are for illustrative purposes, but preprint the names based on the recommended standard testing algorithm for that purpose. Add an extra space for emergency use.
   Use a consistent method for marking off use—a tick (✓), check (✓), cross (✗), or 1 (1).
<table>
<thead>
<tr>
<th>Steps</th>
<th>Actions</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.</td>
<td>Select the appropriate action:</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>IF</strong></td>
<td><strong>THEN</strong></td>
</tr>
<tr>
<td></td>
<td>There are no more blank lines on this page for more patients</td>
<td>➔ Continue with step 10 and 11 and then go to step 3.</td>
</tr>
<tr>
<td></td>
<td>You have seen your last client for the month</td>
<td>➔ Continue with step 10.</td>
</tr>
<tr>
<td></td>
<td>You are conducting another test</td>
<td>➔ Go back to step 6.</td>
</tr>
<tr>
<td>10.</td>
<td><strong>Total Usage based on Use of Test:</strong> For each brand of test (Determine, Uni-Gold, Bionor; other), total the tests by type (screening, confirmatory, and tie breaker).</td>
<td>Do this calculation vertically. Make sure you add all the tests used for each sub-column within the overall brand column (i.e., the total number of tests used for screening, confirmatory, and tie breaker within each brand). For tests that are not used, write “0” in the spaces. Do not leave the spaces blank.</td>
</tr>
<tr>
<td>11.</td>
<td><strong>Total Usage by Brand:</strong> Add the numbers under S, C, T and enter the total number of tests under each brand.</td>
<td>The total usage by brand consists of adding the number of tests used for screening and confirmation and tie-breaker for each brand.</td>
</tr>
<tr>
<td>12.</td>
<td><strong>Total Usage by Brand for the Month (running total):</strong> After the page is full, add the Total Usage by Brand to the previous page running total for the brand to calculate the running total number of tests used by brand for that month.</td>
<td>At the end of the last day of the month, add the total usage by brand for the current page; add that total to the running total usage by brand from the previous page to calculate the total quantity used of each brand for the entire month. When you start to test clients for a new month, start a new running total usage by brand at the bottom of each page for that new month. For tests not used, write “0” in the spaces on the row for “totals.” Do not leave the spaces blank. You will transfer this total usage by brand for the entire month to column D of the LMIS Report and Request for HIV Tests when you report and order.</td>
</tr>
<tr>
<td>13.</td>
<td><strong>Summary of Use of Tests:</strong> To calculate the S, C, and T totals, calculate the total number by use of test (screening, confirmatory, and tie breaker) by adding all the S’s for each brand, all the C’s for each brand, and all the T’s for each brand.</td>
<td>This calculation requires going back to the row of Total Usage based on use of test and adding all the screening, confirmatory, and tie breaker tests (across brands).</td>
</tr>
<tr>
<td>14.</td>
<td><strong>Running Total for the Month:</strong> (under the Summary of Use of Tests) For the running total of the month of use of tests, add the number of tests by use of tests from the summary of each day.</td>
<td>This running total is calculated in a similar way to the way the running total of usage by brand is calculated. The total for this current page is added to the running total from the previous page; the sum of the two becomes the new running total for the month. At the start of a new month, start a new running total for the new month. This number for each of the types (S, C, and T) is transferred to the summary table of HIV Tests by Purpose of Use, Brand and Use of Test on the LMIS Report and Request for HIV Tests.</td>
</tr>
<tr>
<td>Steps</td>
<td>Actions</td>
<td>Notes</td>
</tr>
<tr>
<td>-------</td>
<td>---------</td>
<td>-------</td>
</tr>
<tr>
<td></td>
<td><strong>The task is complete when</strong>—</td>
<td></td>
</tr>
<tr>
<td>□</td>
<td>The purpose of use, facility name, and district are filled in.</td>
<td></td>
</tr>
<tr>
<td>□</td>
<td>The client names and numbers, and results by use of test are entered.</td>
<td></td>
</tr>
<tr>
<td>□</td>
<td>The total number of tests by use of test and by brand are entered.</td>
<td></td>
</tr>
<tr>
<td>□</td>
<td>The running total usage of tests by brand for the month is calculated.</td>
<td></td>
</tr>
<tr>
<td>□</td>
<td>The summary of use of tests is completed, including the running total for the month.</td>
<td></td>
</tr>
<tr>
<td>□</td>
<td>The total quantities of tests organized by purpose of use for brand and use of test during the month are transferred to the LMIS Report and Request Form for HIV Tests.</td>
<td></td>
</tr>
</tbody>
</table>
# JOB AID: COMPLETING THE LMIS REPORT AND REQUEST FOR HIV TESTS

**Task:** Completing the LMIS Report and Request for HIV Tests

**Completed by:** The designated person at the SDP responsible for filling the report and request

**Purpose:**
- To provide logistics data to the central level
- To provide a report on the stock status of HIV tests in the facility
- To order additional HIV tests
- To provide evidence of issue and receipt of HIV tests

**When to perform:** At the end of every order interval (every month)

**Materials needed:** Stock on Hand and Losses/Adjustments data (from stock cards or physical inventory), usage data (from Daily Log for Usage of HIV Tests), calculator, and pen

**Note:** This form is prepared in quadruplicate (one original and three copies). Use a pen to fill out the top copy; make sure the writing clearly shows through on all the copies.

Also, remember to write “0” in the boxes if there was no quantity received or used, or no losses or adjustments. Do not leave boxes blank.

<table>
<thead>
<tr>
<th>Steps</th>
<th>Actions</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td><strong>Reporting Period:</strong> Write the period of reporting with day, month, and year.</td>
<td>e.g., 15/03/2006 to 15/04/2006</td>
</tr>
<tr>
<td>2.</td>
<td><strong>Facility:</strong> Write the name of the facility.</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td><strong>District:</strong> Write the name of the district where the facility is located.</td>
<td></td>
</tr>
</tbody>
</table>

**For each brand of HIV test:**

<table>
<thead>
<tr>
<th>Steps</th>
<th>Actions</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.</td>
<td><strong>Opening Balance:</strong> Write the balance of the beginning of reporting period.</td>
<td>The opening balance can be found on the stock card or in column E/Closing Balance of the LMIS Report and Request for the previous month.</td>
</tr>
<tr>
<td>5.</td>
<td><strong>Quantity Received:</strong> Write the quantity you received during the month.</td>
<td>The quantity received can be found on the stock card. This is the quantity received between the previous order and this order.</td>
</tr>
<tr>
<td>6.</td>
<td><strong>Losses and/or Adjustments:</strong> Write any losses or adjustments that occurred during the month.</td>
<td>Losses and adjustments can be found on the stock card. Be sure to write a minus (–) sign for a loss or a negative adjustment.</td>
</tr>
<tr>
<td>7.</td>
<td><strong>Quantity Used:</strong> Write the quantity that was used during the month covered by the report.</td>
<td>The quantity used can be found on the Daily Log for Usage of HIV Tests. Use the Total by Usage Brand for the Month (running total). Be sure to check the calculations as well.</td>
</tr>
</tbody>
</table>
| 8.    | **Closing Balance:** Write the total stock on hand at the time of reporting. | The closing balance is calculated as opening balance plus quantity received minus quantity used, plus or minus losses or adjustments. Using the column headings on the form, the formula for the calculation is—

\[
E = A + B - C +/– D
\]

You can also verify the closing balance by checking the stock card for the balance at the time of reporting. It is recommended that you conduct a physical inventory of what is actually in the storeroom to ensure that the stock card has been updated. |
<table>
<thead>
<tr>
<th>Steps</th>
<th>Actions</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.</td>
<td><strong>Maximum Stock Quantity:</strong> Calculate and write the maximum stock quantity.</td>
<td>The maximum stock quantity is calculated by multiplying the quantity used during the month by the maximum stock level (2 months in this example). Remember that although the maximum stock level remains 2 months, the actual maximum stock quantities change every time there is an order because the quantities used every month change.</td>
</tr>
</tbody>
</table>
| 10. | **Quantity Needed:** Calculate and write the quantity of the tests needed. | The Quantity Needed is determined by subtracting the closing balance/stock on hand from the maximum stock quantity. Using the column headings on the form, the formula for the calculation is—  
\[ G = F - E \]  
If the calculation gives a negative number (example: – 80), then you already have enough stock so the order quantity is “0.” Be sure to write “0” as the order quantity; do not leave the box blank. |
| 11. | **Remarks and explanations of losses/adjustments:** Write additional comments and any explanations related to losses and adjustments. | For example, if you reported losses or adjustments, write a brief description of the loss/adjustment. |
| 12. | **Summary of Usage of HIV Tests by Purpose of Use, Brand and Use of Test:** Within each purpose of use, record the total tests used by brand and by use of test during the month covered by the report. | Obtain the summaries of total tests used by brand and total tests by use of test (within each purpose of use) from the totals for the month on each Daily Log for Usage of HIV Tests. Remember that each purpose will have a different log book and also, that the monthly total by brand will be on the bottom row and the monthly total by use will be in the summary table. |
| 13. | **Name/Signature/Designation of Person and Date:** The person completing the Report and Request form writes his/her name, designation, and then signs and dates the report. |  |

The task is complete when—

- The reporting period, facility, and district name are filled in.
- The opening balances, quantities received, quantities used, and losses or adjustments are filled in for each product.
- The closing balances are correctly calculated and filled in.
- The maximum stock quantities are correctly calculated and filled in.
- The quantities needed are correctly calculated and filled in.
- The Summary of Usage of HIV Tests Purpose of Use, Brand, and Use of Test is completed.
- The person filling out the report has written his/her name, designation, signature, and the date the report is completed.
JOB AID: COMPLETING THE REPORT FOR RETURNING PRODUCTS

<table>
<thead>
<tr>
<th>Task:</th>
<th>Completing the Report for Returning Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completed by:</td>
<td>The designated person at the SDP responsible for filling the report</td>
</tr>
<tr>
<td>Purpose:</td>
<td>To provide a tracking document for products returned to the central level from the health facility level</td>
</tr>
<tr>
<td>When to perform:</td>
<td>Whenever there are surplus or unusable products that need to be returned to the central level</td>
</tr>
<tr>
<td>Materials needed:</td>
<td>A blank Report for Returning Products, calculator, and pen</td>
</tr>
</tbody>
</table>

Note: This form is a quadruplicate with four copies (an original and three copies). Use a pen to fill out the top copy; make sure the writing clearly shows through on all the copies.

This form is to return either tests or ARV drugs that are in surplus or that are unusable because they are damaged or expired, or will expire before they can be used. Products are in surplus if the SDP has two months or more of stock above the maximum stock level.

<table>
<thead>
<tr>
<th>Steps</th>
<th>Actions</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td><strong>Sent to:</strong> Write the name of the facility to which the products are returned.</td>
<td>This will almost always be the central level.</td>
</tr>
<tr>
<td>2.</td>
<td><strong>Facility returning products:</strong> Write the name of the facility.</td>
<td></td>
</tr>
</tbody>
</table>

For each product being returned:

<table>
<thead>
<tr>
<th>Steps</th>
<th>Actions</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.</td>
<td><strong>Product Description:</strong> Write the name of the product being returned.</td>
<td>As with stock cards, write the form and strength of the product.</td>
</tr>
<tr>
<td>4.</td>
<td><strong>Quantity Returned:</strong> Write the quantity of the product that you are returning.</td>
<td>As with other forms used in the system, record the quantities in order units: tablets, capsules, tests, etc.</td>
</tr>
<tr>
<td>5.</td>
<td><strong>Expiry Date:</strong> Write the date of expiry of the products.</td>
<td>If there are multiple expiry dates for the same product, list all the different expiry dates and the quantities of each product for each of the different expiry dates.</td>
</tr>
<tr>
<td>6.</td>
<td><strong>Reason for Nonuse:</strong> Write the reason you are returning the product (damaged, expired, etc.).</td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td><strong>Name of person returning products/Date/Signature:</strong> The person who is returning the products writes her/his name, and dates and signs her/his name.</td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td><strong>Name of Carrier/Date/Carrier’s Signature:</strong> The person who is transporting the products from the sending facility to the receiving facility writes her/his name and date, and signs her/his name.</td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td><strong>Comments:</strong> The carrier writes any comments, as appropriate.</td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td><strong>Receiver's Name/Date/Receiver's Signature:</strong> The person who receives the products at the receiving facility writes her/his name and date, and signs her/his name.</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td><strong>Comments:</strong> The receiver writes any comments, as appropriate.</td>
<td>In particular, note if there are any discrepancies between the products that were returned and those received by the receiving facility.</td>
</tr>
</tbody>
</table>

The task is complete when—

- The name of the facility to which products are being sent and the name of the facility returning products are filled in.
- The description and quantity of products being returned, the expiry date, and the reason for nonuse are filled in.
- The person filling out the report has written his/her name, signature, and the date.
- The person transporting the products has written his/her name, signature, and the date.
- The person receiving the products has written his/her name, signature, and the date.
GUIDE FOR QUANTIFYING ARV DRUGS
DELIVER
DELIVER, a six-year worldwide technical assistance support contract, is funded by the President’s Emergency Plan for AIDS Relief (PEPFAR) through the U.S. Agency for International Development (USAID).

Implemented by John Snow, Inc. (JSI), (contract no. HRN-C-00-00-00010-00) and subcontractors (Manoff Group, Program for Appropriate Technology in Health [PATH], and Social Sectors Development Strategies, Inc.), DELIVER strengthens the supply chains of health and family planning programs in developing countries to ensure the availability of critical health products for customers. DELIVER also provides technical management of USAID’s central contraceptive management information system.

Recommended Citation

Abstract
Successful implementation and expansion of antiretroviral therapy (ART) services depends on the continuous availability of high-quality antiretroviral (ARV) drugs and on the supply of a wide range of HIV/AIDS-related commodities. The nature of ART and the specific characteristics of ARV drugs and how they are used pose particular challenges for managing the supply chain for ARV drugs. Quantification of health commodities is a process which includes estimating the quantities and the cost of products required to meet customer demand, and to fill the pipeline with adequate stock levels taking into account service delivery capacity, supply pipeline requirements, and resources available for procurement. Although some general considerations for managing the supply chain for ARV drugs are discussed in this guide, the primary focus and purpose of the guide are to describe the process and the methodologies used for quantifying ARV drug needs. Quantification of health commodities is a process which includes estimating the quantities and the cost of products required to meet customer demand, and to fill the pipeline with adequate stock levels taking into account service delivery capacity, supply pipeline requirements, and resources available for procurement.
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<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>3TC</td>
<td>lamivudine</td>
</tr>
<tr>
<td>ABC</td>
<td>abacavir</td>
</tr>
<tr>
<td>AIDS</td>
<td>acquired immune-deficiency syndrome</td>
</tr>
<tr>
<td>AMQR</td>
<td>average monthly quantity required</td>
</tr>
<tr>
<td>ART</td>
<td>antiretroviral therapy</td>
</tr>
<tr>
<td>ARV</td>
<td>antiretroviral</td>
</tr>
<tr>
<td>AZT</td>
<td>zidovudine</td>
</tr>
<tr>
<td>ddI</td>
<td>didanosine</td>
</tr>
<tr>
<td>d4T</td>
<td>stavudine</td>
</tr>
<tr>
<td>EFV</td>
<td>efavirenz</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration (U.S.)</td>
</tr>
<tr>
<td>FTC</td>
<td>emtricitabine</td>
</tr>
<tr>
<td>HAART</td>
<td>highly active antiretroviral therapy</td>
</tr>
<tr>
<td>HIV</td>
<td>human immunodeficiency virus</td>
</tr>
<tr>
<td>IDV</td>
<td>indinavir</td>
</tr>
<tr>
<td>LMIS</td>
<td>logistics management information system</td>
</tr>
<tr>
<td>LPV/r</td>
<td>lopinavir + ritonavir</td>
</tr>
<tr>
<td>MSH</td>
<td>Management Sciences for Health</td>
</tr>
<tr>
<td>NFV</td>
<td>nelfinavir</td>
</tr>
<tr>
<td>NVP</td>
<td>nevirapine</td>
</tr>
<tr>
<td>OI</td>
<td>opportunistic infection</td>
</tr>
<tr>
<td>PEP</td>
<td>post-exposure prophylaxis</td>
</tr>
<tr>
<td>PEPFAR</td>
<td>President’s Emergency Plan for AIDS Relief</td>
</tr>
<tr>
<td>PMTCT</td>
<td>prevention of mother-to-child transmission</td>
</tr>
<tr>
<td>SQV</td>
<td>saquinavir</td>
</tr>
<tr>
<td>STG</td>
<td>standard treatment guidelines</td>
</tr>
<tr>
<td>STI</td>
<td>sexually transmitted infection</td>
</tr>
<tr>
<td>TB</td>
<td>tuberculosis</td>
</tr>
<tr>
<td>TDF</td>
<td>tenofovir</td>
</tr>
<tr>
<td>VCT</td>
<td>voluntary counseling and testing</td>
</tr>
<tr>
<td>VEN</td>
<td>vital, essential, nonessential</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
<tr>
<td>ZDV</td>
<td>zidovudine</td>
</tr>
</tbody>
</table>
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/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/AIDS services. The publication is also dedicated to friends and counterparts who have worked with DELIVER, 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/AIDS and laboratory commodities, we recognize that comprehensive HIV/AIDS and laboratory programs require the supply chain to manage and deliver a broad range of several hundred public health commodities.

The 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—especially Mark Rilling and Sharmila Raj—for their encouragement and advice and their commitment to improving HIV/AIDS laboratory and public health programs through logistics.

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The DELIVER Communications Group edited, designed, and produced the Resources. Their patience, persistence, insight, and support are much appreciated. In particular, appreciation goes to Heather Davis, communications manager; Pat Shawkey, publications manager; Pat Spellman, editor; Gus Osorio, art director; Kathy Strauss, Paula Lancaster, and Susan Westrate, graphic designers; Erin Broekhuysen, communications strategist; Delphi Lee, JSI assistant webmaster; José Padua, DELIVER web manager; Madeline McCaul, communications officer; Jessica Philie, publications coordinator; and Jacqueline Purtell, communications coordinator.
A major challenge to initiation and expansion of antiretroviral therapy (ART) services in resource-poor countries that have been most affected by the HIV/AIDS epidemic has been the limited capacity of health commodity supply chains to ensure a reliable supply of the products at service delivery sites to support HIV prevention, care, and treatment programs. Successful provision of ART services depends not only on the continuous availability of high-quality antiretroviral (ARV) drugs but also on the supply of a range of HIV/AIDS-related commodities.

These commodities include drugs for the treatment of sexually transmitted infections, tuberculosis (TB), and other opportunistic infections (OIs); HIV tests and other laboratory reagents; contraceptives; condoms; protective gear for infection prevention and health worker safety; and a host of consumable medical and laboratory supplies. A significant number of public sector programs in resource-poor countries urgently need enhanced capacity most supply chain management functions, including specifically in quantification, financing, procurement, and delivery of HIV/AIDS-related commodities. Global efforts to coordinate quantification, financing, and procurement are also critical and must complement country-based initiatives.

The nature of ART and the specific characteristics of ARV drugs and how they are used pose particular challenges for managing the supply chain for ARV drugs. Although some general considerations for managing the supply chain for ARV drugs are discussed in this guide, the primary focus and purpose of the guide are to describe the process and the methodologies used for quantifying ARV drug needs. Further technical aspects of managing the supply chain for ARV drugs are discussed in depth in other sections of the DELIVER Guidelines for Managing the HIV/AIDS Supply Chain.

This guide for quantifying ARV drugs draws from the collective experience of DELIVER logistics advisors who have been involved in a range of activities to improve management of the supply chains for HIV/AIDS commodities in several countries that are hardest hit by the epidemic. DELIVER’s experience indicates that two of the most critical supply chain interventions for ART programs at this time are the need to:

- Establish robust data collection and reporting systems to improve the availability and quality of data on ART services and commodities.
- Build capacity in quantification of ARV drug requirements at the country and program levels to enhance informed decision making regarding financing and procurement of commodities, thus maximizing opportunities for continuous product availability in a country.

The DELIVER experience and lessons learned in quantification of ARV drugs in eight countries have been incorporated into the step-by-step approach to quantification presented in this guide. Illustrative examples from Excel spreadsheets that were used in quantifying drug requirements for a national ART program are attached in the appendix to this guide. It is important to recognize that each country, each program, and each quantification will be unique as programs mature, as technologies and clinical practice evolve, as new drug formulations become available, and as logistics management information systems (LMIS) improve to enable more evidence-based quantifications. This guide is, therefore, a work in progress that will be reviewed and updated over time to reflect the growing body of knowledge and the best practices in ART and on management of ARV drug supply chains.
INTRODUCTION TO QUANTIFICATION

Quantification of health commodities is a process that includes estimating the quantities and the cost of products as required to meet customer demand and to fill the pipeline with adequate stock levels. The process takes into account the service delivery capacity, supply pipeline requirements, and resources available for procurement. Quantification consists of four distinct steps: forecasting demand, estimating requirements, calculating the costs for procuring the requirements, and, if needed, adjusting the final quantities to procure according to the amount of funding available.

The results of a quantification may be used (a) to calculate specific order quantities and to plan shipment schedules for short-term procurement planning, and (b) to assist in medium- to long-term program planning and resource mobilization efforts.

DEFINITION OF TERMS
Given the level of precision required to conduct accurate quantifications, it is important to clarify the use of specific terms within the context of this document that may be used and understood differently in other contexts.

CUSTOMER
Within the context of quantification of health commodities, the customer is the end user who is understood to be the patient, the client, or the provider who will ultimately receive, use, or consume the product within the forecast period.

CUSTOMER DEMAND
Therefore, customer demand refers to the specific quantities of the product to be dispensed or used to be able to meet customers’ requests or their actual rather than their potential demand for health services within the forecast period.

PRODUCT WASTAGE
Product wastage is the estimated quantity of product that is expected to be wasted through normal usage or through nonuse. Wastage through normal use or nonuse can occur, for example, through spillage, through incorrect measurement or damage during use, or by accounting for quantities of a product that may be returned by patients and that cannot be re-used or dispensed to other patients. Product wastage is based on an accepted standard percentage of total product consumption.

STEPS IN QUANTIFICATION
Figure 1 represents the steps in the quantification process.
FORECASTING DEMAND

Forecasting demand means estimating the quantity of products (e.g., drugs to be dispensed, HIV tests or laboratory reagents to be used) to meet customer demand for a future period of time. For health commodities, the number of customers to be served and the cases to be treated, along with the forecasted demand, may need to be adjusted to reflect (a) the scope of the quantification, which may be a national-level quantification or may be for a specific program, service sector, geographic region, level of service, or patient target group; (b) the purpose of use within the quantification (for example, drugs for both ART and prevention of mother-to-child transmission [PMTCT] services), or HIV tests for only voluntary counseling and testing (VCT) and PMTCT services; and (c) the program’s service capacity according to the volume of services that can be provided, given the existing infrastructure, staff availability and staff skills, and customer access to services.

In the case of HIV tests and laboratory reagents and supplies, the forecast may need to include additional quantities for quality control and training, in addition to client testing. For products that have multiple uses, it may be necessary to forecast demand separately for each use. Examples of forecasting demand separately could include forecasting demand for an antibiotic prescribed for treating sexually transmitted infections (STIs) and OIs under different treatment guidelines, or forecasting usage of an HIV test for diagnostic or confirmatory testing under different testing protocols for PMTCT, clinical diagnosis, or VCT.

ESTIMATING COSTS

The term estimating costs involves calculating the cost of procuring all the product requirements. In addition to the commodity cost, other procurement, shipping, handling, customs clearance, storage, and distribution costs may also be included in the total cost estimate.

DETERMINING QUANTITY TO PROCURE

Determining the quantity to procure consists of identifying the quantities of products to be procured. If the cost estimate does not exceed the total funds available, then this step is straightforward and requires little to no adjustment of the estimated requirements. In most cases, the quantity to procure will equal the requirements estimate. If, however, the cost estimate is greater than the available funding envelope, an adjustment must be made to the estimated requirements, either by reducing the number of items to be procured or by recalculating the quantities required of each individual product.
For most public health programs, this step involves prioritizing the items to be purchased according to the conditions to be treated or the people to be served, and then reducing the quantity to procure to fit available funds. In such cases, a variety of methods can be used to arrive at the final quantity of product to be procured, including the use of epidemiological profiles, or ABC and VEN (vital, essential, nonessential) analyses. For HIV/AIDS programs, this step may result in a reduction of the number of people who can be tested for HIV infection or the number of patients who can initiate ART within the period of the forecast.

FORECASTING METHODOLOGIES

In general, the methodology that is selected for forecasting the future demand for services and commodity needs is based on the availability and quality of data on (a) the rate of consumption of drugs or commodities used and (b) the number and type of patients receiving services, as well as on program policies and expansion plans. The following types of data may be used to guide the forecast:

Demographic data based on characteristics of the target population (e.g., age, sex, geographic location, and urban or rural location)

- Morbidity data on prevalence or incidence of disease or infection in the target population
- Service statistics data on the number of service delivery sites, the volume of services or number of patients per site, and the type of service received
- Logistics data on consumption, losses, and adjustments to inventory, and the stock on hand at the various levels of the in-country supply chain.

For new and expanding programs or services and for existing programs for which those types of data may be unavailable, unreliable, or not predictive of future demand, forecasts may be based on program targets, such as the number of patients expected to access and receive treatment within the period of the forecast. Targets for expanding programs should be based on realistic service delivery and supply chain capacity, as well as on available resources. Although forecasts based on program targets are commonly used to determine commodity needs and cost estimates for procurement, program targets may also be based on the number of patients who could be treated given a specific amount of funding available and the commodity cost per patient.

Forecasts that are based on demographic, morbidity, or target data alone will most often overestimate drug requirements because they do not take into account the actual volume of services being provided or that can be provided, or the quantities of commodities being dispensed or used. Wherever possible, service statistics data on the actual number of patients being treated, as well as logistics data on the actual quantities of drugs dispensed to patients or the actual quantities of commodities used, should be incorporated into the forecast.

THE CONSUMPTION-BASED METHODOLOGY

The consumption-based methodology uses logistics data on consumption of commodities in the past as a basis for projecting future needs. Estimates of increases in consumption or other changes in consumption for each product during the period of the forecast are based on past trends in consumption or product usage. Use of the consumption-based methodology requires the availability of data on the quantities of drugs actually dispensed to patients or on the commodities used at service delivery points over a specified period. In many cases, timely and accurate consumption data are not available, and, even if they are available, consumption data alone will not be indicative of future demand in new programs and in expanding programs. Assumptions will need to be made about the rate of program growth, about prescribing and dispensing practices, and about patient needs to complete the quantification.
**THE ADJUSTED CONSUMPTION METHODOLOGY**

The *adjusted consumption methodology* is an adaptation of the consumption-based methodology that uses the consumption data of one or more facilities that have reliable data and extrapolates from that data to estimate the quantities of commodities needed at other, similar facilities for which no data or unreliable data exist. Again, this methodology requires the availability of timely and accurate consumption data on quantities of drugs dispensed to patients or quantities of commodities used at one or more service delivery sites.

**THE MORBIDITY-BASED METHODOLOGY**

In the *morbidity-based methodology*, the estimation of commodity needs is based on the application of standard treatment guidelines, testing algorithms, or other treatment protocols to the projected number of patients expected to receive treatment or services within the forecast period. The projected number of patients to be forecasted may be based on demographic data, morbidity data, service statistics data, program targets, or a combination of those data.

Using the morbidity-based methodology for estimating commodity requirements requires that data on the actual number of patients treated or services provided and the estimated number of new patients to be diagnosed and treated or services to be provided within the period of the forecast must be available or must be arrived at through informed assumptions. Standard treatment guidelines, testing algorithms, or other policy guidelines should be clearly documented, disseminated, and assumed to be adhered to by all service providers who have been adequately trained. The accuracy of morbidity-based forecasts depends on the degree to which standard treatment guidelines (STGs) are followed and on the availability of prescribed drugs or commodities when they are needed.

In practice, forecasts may be conducted using two or more types of data and a combination of methodologies. For example, the results of a consumption-based forecast and a morbidity-based forecast may be compared and adjusted to arrive at a best estimate of future commodity requirements.

**THE IMPORTANCE OF STANDARDIZATION IN QUANTIFICATION**

A critical prerequisite for conducting quantification for any essential medicine is the existence of clear, well-defined STGs for defining the specific use of individual drugs for treating illnesses and conditions. The importance of having STGs in place is magnified in the case of new, rapidly expanding ART programs for the following reasons:

- The number of experienced service providers is small relative to the number of treatment sites, and STGs are an essential tool for helping new service providers deliver quality care for patients.

- ART service provision consists of providing three or more different ARV drugs in deliberate combinations and doses. Even a slight deviation from predefined combinations can have a negative impact on the health of the patient by reducing the efficacy of a given product or by resulting in adverse side effects.

- In resource-limited environments a public health approach is used to develop the criteria for product selection and STG development, meaning that the choice of drug combinations not only are based on safety and efficacy criteria but also include cost considerations. Cost considerations are included so that programs are able to treat as many patients as possible with available funding. Without STGs, physicians may choose unaffordable ARV drug alternatives, which will increase costs for programs and individuals and which could ultimately compromise product availability.
Standardization of treatment guidelines is especially critical in the context of quantification. In the absence of quality logistics data, quantification will likely be conducted using the morbidity-based methodology. Standard treatment guidelines must exist and must be clearly documented and disseminated to enhance the accuracy of the quantification using this method. Because ARV drugs are provided in varying combinations to treat patients, quantification is virtually impossible without the existence of STGs. DELIVER has worked in several countries where STGs for ART have been incomplete or have been inconsistent at the time of the quantification, thereby delaying quantification and procurement until the STGs could be finalized.
Successful ART depends on lifelong patient adherence to prescribed ARV drug regimens and on maintenance of a full supply of ARV drugs at ART sites. The threat of drug resistance and changes in patients’ responses to treatment over time make it imperative to ensure a reliable, flexible, and uninterrupted supply of quality ARV drugs that respond to patient needs and that are available when and where patients need them at an acceptable cost. One must understand the specific characteristics of ARV drugs, the ways in which they are used, and the special requirements for storing and handling them to achieve those goals. This knowledge must be incorporated into the quantification of needs to ensure procurement of the right quantities of the right drugs.

**CHARACTERISTICS OF ARV DRUGS**

ART treatment with ARV drugs has several characteristics that affect the management of the commodities and that pose unique challenges in quantification. Those characteristics include, but are not limited to, the following:

- ART requires lifelong treatment.
- A single ARV drug regimen requires a combination of at least three different drugs, often from different manufacturers, to be available concurrently.
- Each drug is often used in more than one regimen.
- The choice of regimens includes considerations of weight and toxicity, factors wholly unique to individual patients and factors that cannot be predicted based on data currently available in resource-poor settings. This unpredictability is particularly true for pediatric patients, where changes in weight vary significantly even within a population and where body surface is a factor in calculating dosage.
- Treatment failure is difficult to predict and to diagnose in resource-poor settings.
- The cost of treatment is still a barrier and varies significantly by source and by the type of regimens in use (many first line regimens are generally less costly than second line regimens).

Lifelong ART, which is also referred to as highly active antiretroviral therapy (HAART), requires treatment with a combination of three ARV drugs. Single-drug formulations and fixed-dose combinations of two or three ARV drugs are available for completing prescribed treatment regimens and for facilitating patient adherence. A reliable and uninterrupted supply of ARV drugs is absolutely critical given that more than 90 to 95 percent adherence to ART is required for treatment regimens to be effective over the long term. Lower levels of adherence are associated with the development of drug-resistant HIV. In a twice-a-day regimen, this factor means that less than one dose every two weeks can be missed.

Different doses of some ARV drugs are available to enable adjustment of treatment regimens to individual patient needs—for example, stavudine (20 mg, 30 mg, or 40 mg) and didanosine (25 mg, 100 mg, or 200 mg). Single-drug formulations must be available for substitution within first- and second line regimens because some patients develop side effects or toxicity to individual drugs, and because three completely different ARV drugs for second line regimens must be available for patients who develop resistance to first line
drugs. Specific formulations for pediatric treatment regimens include oral suspensions (syrups) and children’s dosages, which are adjusted for weight and body surface area measurements. In addition, quantifications will need to be updated to accommodate procurement of new ARV drug formulations and more user-friendly fixed-dose combinations as they become available on the market.

ARV drugs are produced in tablet and capsule form and in syrup, oral solution, and oral suspension for pediatric ART. Table 1 lists common ARV drugs for adults and children, including the ARV drug class, drug name, and currently available formulations. Table 2 provides examples of fixed-dose combinations of ARV drugs.

### Table 1. Examples of Single Drug Formulations (Illustrative List Only)

<table>
<thead>
<tr>
<th>Adult and Adolescent Formulations</th>
<th>Pediatric Formulations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nucleoside Reverse Transcriptase Inhibitors (NRTIs)</strong></td>
<td></td>
</tr>
<tr>
<td>Abacavir (ABC) 300 mg tablet</td>
<td>Abacavir (ABC) oral solution, 20 mg/mL bottle</td>
</tr>
<tr>
<td>Didanosine (ddI) 125 mg, 200 mg, 250 mg, and 400 mg enteric-coated capsules</td>
<td>Didanosine (ddI) 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg chewable tablets</td>
</tr>
<tr>
<td>Didanosine (ddI) oral suspension, 10 mg/mL bottle</td>
<td>Lamivudine (3TC) 10 mg/mL bottle</td>
</tr>
<tr>
<td>Lamivudine (3TC) 150 mg tablet</td>
<td>Lamivudine (3TC) oral solution, 10 mg/mL bottle</td>
</tr>
<tr>
<td>Stavudine (d4T) 15 mg, 20 mg, 30 mg, and 40 mg capsules</td>
<td>Stavudine (d4T) oral solution, 1 mg/mL bottle</td>
</tr>
<tr>
<td>Zidovudine (AZT or ZDV) 100 mg and 250 mg capsules, 300 mg tablet</td>
<td>Zidovudine (AZT or ZDV) syrup, 10 mg/mL bottle</td>
</tr>
<tr>
<td>Etricitabine (FTC) 200 mg capsule</td>
<td></td>
</tr>
<tr>
<td><strong>Nucleotide Reverse Transcriptase Inhibitors (NtRTIs)</strong></td>
<td></td>
</tr>
<tr>
<td>Tenofovir (TDF) 300 mg tablet</td>
<td></td>
</tr>
<tr>
<td><strong>Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)</strong></td>
<td></td>
</tr>
<tr>
<td>Efavirenz (EFV) 50 mg, 100 mg, and 200 mg capsules</td>
<td>Efavirenz (EFV) 600 mg tablet</td>
</tr>
<tr>
<td>Nevirapine (NVP) 200 mg tablet</td>
<td>Nevirapine (NVP) oral suspension, 10 mg/mL bottle</td>
</tr>
<tr>
<td><strong>Protease Inhibitors (PIs)</strong></td>
<td></td>
</tr>
<tr>
<td>Indinavir (IDV) 100 mg, 200 mg, 333 mg, and 400 mg capsules</td>
<td></td>
</tr>
<tr>
<td>Lopinavir + ritonavir (LPV/r) 133.3 mg/33.3 mg capsules</td>
<td>Lopinavir + ritonavir (LPV/r) 80 mg/mL + 20 mg/mL oral solution</td>
</tr>
<tr>
<td>Saquinavir (SQV) 200 mg soft gel capsule, 200 mg hard gel capsule</td>
<td></td>
</tr>
<tr>
<td>Nelfinavir (NFV) 250 mg tablet</td>
<td></td>
</tr>
<tr>
<td>Ritonavir 100 mg capsule, 80 mg/mL oral solution</td>
<td></td>
</tr>
</tbody>
</table>

Note: Lopinavir + ritonavir (LPV/r) = Kaletra®

**Protease Inhibitors (PIs)**

- a. Lopinavir exists in co-formulation with ritonavir (LPV/r = Kaletra®) as a boosted protease inhibitor.
- b. Ritonavir is a protease inhibitor that can be used alone or in combination with other protease inhibitors (lopinavir, indinavir, or saquinavir) to increase their potency, thereby allowing lower doses to be used. Lower doses can reduce the frequency and severity of side effects.
More information on suppliers, packaging, storage, shelf life, and pricing of those and other ARV drugs is available from *ARV Drug Logistics Fact Sheets* (DELIVER 2006). The World Health Organization's publication, *Scaling Up Antiretroviral Therapy in Resource-Limited Settings: Treatment Guidelines for a Public Health Approach* (WHO 2003) has additional information on adult and pediatric dosing regimens and on prescribing guidelines. Those lists are not intended to be exhaustive, and readers should refer to in-country standard treatment guidelines, and to other sources for up-to-date information on which drugs are available and approved for use in particular countries.

A major barrier to expanding access to ART in resource-limited countries has been the high cost of ARV drugs. Costs for ARV drugs vary significantly, often depending on whether they are produced by originator manufacturers or generic manufacturers. Originator ARV drugs are generally more expensive than generic drugs, with a few exceptions. Some drug combinations are available only from generic manufacturers (e.g., most triple-fixed-dose combinations, with a few exceptions, are generic) or from originator manufacturers (e.g., LPV/r is produced as Kaletra).

Voluntary licensing and price reductions by both originator manufacturers and generic manufacturers have resulted in reduced cost of ARV drugs for resource-limited countries with high HIV prevalence and morbidity. Special provisions, including fast tracking of the U.S. Food and Drug Administration (FDA) approval process, will allow FDA approval of generic manufactured drugs and, hence, will allow their procurement with U.S. government funds for Africa and for developing countries through the President’s Emergency Plan for AIDS Relief (PEPFAR). Therefore, updated information on local and international pricing for both generic and originator ARV drugs needs to be used for completing the quantification.

**TYPES OF ART AND COMMON ARV DRUG REGIMENS**

Antiretroviral therapy regimens for the prevention of mother-to-child transmission of HIV for patients with HIV/TB co-infection and for post-exposure prophylaxis (PEP) should be included in national ART guidelines, in addition to the standard first line and second line treatment regimens for adults and children (see table 3). Frequently, national quantifications will forecast demand for all the different regimens and purposes for ART as part of the overall requirements estimation.

Table 3 illustrates how a single drug often overlaps in use between several different regimens. For example, according to the list in the table Lamivudine (or 3TC) is the backbone of all the adult and pediatric first line regimens, while Didanosine (or ddI) is the backbone of all the adult and pediatric second line regimens. Miscalculations in estimating requirements of a drug such as 3TC or ddI in a country with regimens similar to those listed in the table will have a widespread effect on the majority of ARV drug regimens, while miscalculations in estimating requirements of a drug such as Saquinavir may not have such a widespread effect.

**TABLE 2. EXAMPLES OF FIXED DOSE COMBINATION DRUGS (ILLUSTRATIVE LIST ONLY)**

<table>
<thead>
<tr>
<th>Double-Fixed-Dose Combination Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stavudine 30 mg + lamivudine 150 mg tablet (d4T/3TC)</td>
</tr>
<tr>
<td>Stavudine 40 mg + lamivudine 150 mg tablet (d4T/3TC)</td>
</tr>
<tr>
<td>Zidovudine 300 mg + lamivudine 150 mg tablet (AZT/3TC or ZDV/3TC)</td>
</tr>
<tr>
<td>Tenofovir 300 mg + emtricitabine 200 mg tablet (TDF/FTC)</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Triple-Fixed-Dose Combination Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stavudine 30 mg + lamivudine 150 mg + nevirapine 200 mg tablet (d4T/3TC/NVP)</td>
</tr>
<tr>
<td>Stavudine 40 mg + lamivudine 150 mg + nevirapine 200 mg tablet (d4T/3TC/NVP)</td>
</tr>
<tr>
<td>Zidovudine 300 mg + lamivudine 150 mg + abacavir 300 mg tablet (ZDV/3TC/ABC)</td>
</tr>
</tbody>
</table>
### TABLE 3. EXAMPLES OF COMMON ARV DRUG REGIMENS (ILLUSTRATIVE LIST ONLY)

<table>
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<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>d4T + 3TC + NVP</td>
<td>TDF + ddi + LPV/r</td>
<td>d4T + 3TC + EFV</td>
<td>d4T + 3TC + NVP</td>
<td>ABC + ddi + NFV</td>
<td>d4T + 3TC + ABC</td>
<td>ZDV + 3TC (mother)</td>
<td>High-risk exposure</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ZDV + 3TC (infant)</td>
<td>ZDV + 3TC + NFV</td>
</tr>
<tr>
<td>d4T + 3TC + EFV</td>
<td>TDF + ddi + SQV/r</td>
<td>d4T + 3TC + ABC</td>
<td>d4T + 3TC + EFV</td>
<td>ABC + ddi + LPV/r</td>
<td>ZDV + 3TC + ABC</td>
<td>ZDV + 3TC (infant)</td>
<td>ZDV + 3TC + NFV</td>
</tr>
<tr>
<td>d4T + 3TC + NFV</td>
<td>TDF + ddi + IDV/r</td>
<td>d4T + 3TC + SQV/r</td>
<td>d4T + 3TC + NFV</td>
<td>ABC + ddi + SQV/r</td>
<td></td>
<td>NVP 200 mg tablet (mother)</td>
<td>Low-risk exposure ZDV + 3TC</td>
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<tr>
<td>d4T + 3TC + LPV/r</td>
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<td></td>
<td></td>
<td></td>
<td>NVP 10 mg/ml syrup (infant)</td>
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<tr>
<td>ZDV + 3TC + NVP</td>
<td>ABC + ddi + LPV/r</td>
<td>ZDV + 3TC + EFV</td>
<td>ZDV + 3TC + NVP</td>
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<tr>
<td>ZDV + 3TC + EFV</td>
<td>ABC + ddi + SQV/r</td>
<td>ZDV + 3TC + ABC</td>
<td>ZDV + 3TC + EFV</td>
<td></td>
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<tr>
<td>ZDV + 3TC + NFV</td>
<td>ABC + ddi + IDV/r</td>
<td>ZDV + 3TC + SQV/r</td>
<td>ZDV + 3TC + NFV</td>
<td></td>
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<td></td>
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<tr>
<td>ZDV + 3TC + LPV/r</td>
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<tr>
<td>TDF + 3TC + NVP</td>
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<tr>
<td>TDF + 3TC + EFV</td>
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CHALLENGES SPECIFIC TO FORECASTING DEMAND FOR ARV DRUGS

Forecasting demand for ARV drugs in the current environment in resource-poor settings is challenging for several reasons. The first reason is that ART programs are new and growing and are, therefore, unpredictable. The rate of new patient uptake for ART is uncertain in many cases, and it often depends on a multitude of factors, including stigma, knowledge of HIV status, availability of HIV testing services, and nature of the epidemic. Furthermore, use of ARV regimens — even as defined by standard treatment guidelines—is unpredictable.

In most countries, ARV drug regimens consist of at least three separate drugs, and the initial use of those regimens is influenced by patients’ previous ARV drug history, by other co-existing infections or conditions, by provider prescribing patterns, by drug supply, and by other factors. In addition, the drugs within a regimen must be adjusted over time to capture the changing needs of patients that are caused by side effects and toxicities to individual drugs, by changing body weight, by pregnancy, by HIV/TB co-infection, and by treatment failure and drug resistance. The regimen may also change to meet the special needs of pediatric patients. Forecasts often also need to account for patients on nonstandard ARV drug regimens such as patients who are not treatment-naïve or who may have entered the program already on ART, as well as patients who are on individualized salvage therapy.

Estimates of the number of people expected to be placed on ART within the period of the forecast should be based on prevalence of disease, actual numbers of patients on treatment, and program expansion plans. Where program targets have been established, it is critical that assessments of actual service capacity to reach and treat patients, of supply chain capacity to ensure the availability of the drugs for the patients who need them (and where and when they need them), and of the financial resources available for procurement should be taken into consideration. In several programs, overly optimistic or unrealistic treatment targets have led to the overestimation of drug requirements. This overestimation has resulted in excess procurement and, ultimately, in wastage of products that could not be distributed or used before they expired.

Forecasting demand for ARV drugs requires the following data to be available, or arrived at through informed assumptions:

- The total number of existing patients on ART stratified by number or proportion of adult versus pediatric patients
- The estimated number of new patients to be diagnosed and treated within the period of the forecast, which should be estimated separately for adult and pediatric patients
- The percentage of patients who will be on each of the ARV drug regimens listed in the national standard treatment guidelines, including (a) the specific information on the percentage of patients currently on first line and second line regimens, (b) the rate of single-drug substitutions because of toxicities and side effects, and (c) the rate at which patients will need to make a complete regimen switch from a first line regimen to a second line regimen because of treatment failure or drug resistance

The accuracy of forecasts will rely heavily on the completeness and reliability of data and on the level of adherence to STGs. To enhance the likelihood of accurate quantifications using the morbidity-based methodology, STGs should be clearly documented and disseminated, and all service providers should be adequately trained in ART.
Given the constraints in the type and quality of data available, multiple assumptions will need to be made about expected uptake in services, capacity, and quality of service delivery; rates of change in treatment regimens; procurement and supplier lead times; and status of the in-country supply pipeline. A consultative process with ART stakeholders should be followed to enhance accuracy and to ensure that the final quantities to order have been developed with input from a range of ART implementers (program planners, procurement specialists, clinical experts, pharmacists, nurses, counselors, and warehouse managers). Documenting the sources of information and input from key individuals who are used to inform the assumptions for the quantification is important. The quantification should be reviewed and updated at least every three to six months, as well as when any of the major assumptions change.

The following are examples of the types of issues about which assumptions may need to be made:

- Availability and continuity of funding for procurement of ARV drugs
- Application of standard treatment guidelines by prescribers at all ART sites
- Continued availability of ARV drugs at ART sites so that patients requiring a change in regimen will be able to substitute or switch, when needed
- Service delivery capacity, patient access to treatment and uptake, patient adherence, and follow up
- Length of time before patients will experience side effects, toxicity, treatment failure, and drug resistance to ARV drugs
- Patient weight before treatment and length of time on ART before weight gain
- Procurement and supplier lead times and shipment schedules
- Consumption and stock levels of ARV drugs
- Supplier production capacity to meet demand.
The following approach to quantification is based on the experience of DELIVER advisors in conducting ARV drug quantifications in eight countries. The challenges and lessons learned from this experience have been incorporated into the step-by-step approach to quantification presented here. Examples from Excel spreadsheets are used to illustrate the steps in developing a quantification for a national ART program.

The quantification exercise should be conducted as a consultative process in collaboration with ART stakeholders, including policymakers, program managers, and service providers, as well as clinical, pharmaceutical, and procurement experts. The results of the quantification may be used to inform product selection, to inform policy and technical decisions, and to facilitate mobilization and allocation of financial resources for procurement of ARV drugs. Given the relatively early stage of scale-up in the countries most affected by the HIV/AIDS epidemic, the quantification should be reviewed and updated every six months to reflect actual program performance, changes in policy or clinical practice, and patient response to treatment, as well as to be able to take advantage of new drug formulations on the market and ongoing price reductions.

**PREREQUISITES TO QUANTIFICATION**

The purpose and scope of a quantification, and the amount of data available that can be used, will vary from program to program. Prior to beginning the quantification process, it is critical to ensure that these “prerequisites” are as clear and well-defined as possible. Investing time at this stage in the process will help lay the foundation for effective, long-term forecasting.

**DEFINE THE SCOPE AND PURPOSE OF THE QUANTIFICATION**

The scope of the quantification will depend on various political, programmatic, financial, and environmental factors. National-level quantification may be required, or separate quantifications may be needed for different sectors, programs, target populations, geographic regions, funding sources, or supply chains. The number, type, and level of the facilities to be covered by the quantification should also be defined.

Although one standardized methodology for quantification of all ARV drug requirements for a country or program is recommended to facilitate application of STGs and to minimize duplication between multiple sources of supply, procurement, and distribution of commodities, establishing such a methodology may not always be possible. Some examples of quantifications that have been conducted include the following:

- National-level quantification to meet the needs of the whole country
- Quantifications by health sector (public sector, nongovernmental, or private sector)
- Quantifications by program (e.g., national PMTCT, or ART programs; PMTCT Plus, pilot ART sites, or other donor-supported ART services)
- Quantifications by target population (e.g., high prevalence, at-risk population groups such as intravenous drug users or commercial sex workers)
- Quantifications by geographic region (ART services may exist or be supported in certain regions of the country and not in other regions)
• Quantifications by funding source (government or donor organizations that fund procurement of commodi-ties may require separate quantifications)

• Quantifications by supply chain (quantification for products that may be managed through separate funding, procurement, and distribution systems, for example, through a network of rural-based, church organizations).

The purpose of the quantification must be identified. The following are examples:

• Is the quantification to inform donors about funding requirements and to advocate for resource mobilization for ARV drug procurement?

• Is the quantification to estimate ARV drug needs and to assess the stock status of the in-country supply pipeline so that supply imbalances can be identified and corrected?

• Is the quantification to support an estimate of commodity procurement, storage, and distribution costs?

The quantification exercise should answer the following key questions:

• How many patients can be treated with available funds? For how long can they be treated? Or, conversely, how much would it cost to treat a target number of patients within a given time period?

• How long will current stocks last given current consumption and expected rates of growth?

• What quantities of ARV drugs need to be procured, and when are the quantities needed to avoid stockouts and to support program expansion?

DESCRIBE THE PROGRAM

Before conducting the quantification, one must consider existing information about the ART program plans, the service capacity of the program, and the ARV drug logistics system to identify service delivery and supply chain issues affecting the demand for and supply of ARV drugs. If information on ART program activities and plans, service capacity, and the ARV drug logistics system is not available, an assessment of service delivery and supply chain capacity will need to be conducted before a quantification of ARV drug requirements can be attempted.

The scope and activities of the ART program should be described—that is, the range of ART interventions being provided (e.g., adult and pediatric ART, PMTCT, HIV/TB, PEP); the model of care; the program leadership and management system; the STGs for ART; the number and location of ART sites; the patient enrollment criteria; and the number of patients on ART.

DETERMINE THE PERIOD OF THE FORECAST

Medium-term forecasts of ARV drug needs for two to five years are recommended to assist in program planning and in mobilizing financial resources for procurement of ARV drugs to support program expansion. The quantification and the costing of commodity requirements for procurement with available funds for a one-year period are recommended for short-term procurement planning and should include specific quantities of each product to be procured and a shipment delivery schedule for the year. Because of the rapidly changing environment in which scale-up of ART is occurring, procurement plans for one year at a time
are recommended, and such plans should be revised and updated every three to six months to reflect actual services provided and quantities of commodities used.

**DETERMINE THE TARGET NUMBER OF PATIENTS ON ART FOR EACH FORECAST YEAR**

Although targets based on population and HIV prevalence data alone may be useful for advocacy or resource mobilization, they should not be used for procurement planning. Those targets tend to highly overestimate commodity requirements because they are not based (a) on any actual services provided or drugs dispensed, (b) on an assessment of realistic service delivery capacity or supply chain capacity, or (c) on resources available to support program growth.

Nationally accepted program targets that are based on population and HIV prevalence data should be reviewed and modified on the basis of previous assessments, evidence, or considerations of national- and facility-level “readiness” or capacity to provide ART services and manage the ARV drug supply chain. Realistic patient target numbers should be based on the following:

- Current level of service provision (number of sites with trained providers, infrastructure, laboratory services, and number of patients already on ART) and plans for expansion
- Current status of ARV drug supply and product availability at ART sites (stock status assessment of months of stock on hand at the facility and at the national level)
- Plans for financing and procuring ARV drugs (sources and amounts of funding available for procurement of ARV drugs, disbursement schedules, procurement mechanisms, and lead times).

Assumptions about the percentages of the target population that may be eligible for ART and also able to access ART for each forecast year should be built into the quantification. Different patient target numbers may need to be quantified for estimating commodity requirements and cost implications under different scenarios.

**COLLECT THE REQUIRED DATA**

Key data and information must be collected on ART program activities, treatment guidelines, expected rates of change in patient treatment regimens, and ARV drug supply required to undertake the quantification.

For ART program planning, management, and policy information, the steps are as follows:

**Step 1.** Identify the type of program (e.g., ministry of health, nongovernmental organization, mission or religious, or pilot or research).

**Step 2.** List all ART services provided (PMTCT; PMTCT Plus; adult, adolescent, and pediatric HAART; HIV/TB; PEP; treatment of HIV/TB co-infected patients).

**Step 3.** Describe the model of care (the level and type of facilities where ART is provided such as a primary, secondary, tertiary, or community-based facility).

**Step 4.** Determine the national ART guidelines, including STGs that are recommended and approved for the following:

- Adult and pediatric first line treatment regimens with single-drug substitutes for side effects, toxicity, pregnancy, and HIV/TB co-infected patients
• Adult and pediatric second line treatment regimens for patients who develop treatment failure or viral resistance
• PMTCT (short-course therapy and single-dose nevirapine regimens for both mothers and newborns)
• Treatment regimens for patients with HIV/TB co-infection
• PEP (regimens for prophylaxis of high-risk exposure and low-risk exposure)

Step 5. Verify that all ARV drugs required in the STGs are on the national essential medicines list and are currently registered for importation and use in the country. Include all presentations of each ARV drug as follows:
• Form and strength (tablet, capsule, oral suspension, and all dosages available)
• Single-drug formulations and fixed-dose combination drugs
• Pediatric formulations

Step 6. Identify suppliers for each ARV drug formulation.

For drug financing and pricing information, the following steps are necessary:

Step 1. Identify all sources of financing for ARV drugs (the government, international donor agencies, foundations, and pharmaceutical company donation programs such as Boehringer Ingelheim’s Viramune®).

Step 2. Determine the amount and duration of each financial commitment for ARV drug procurement.

Step 3. Identify the procurement mechanisms and drug suppliers for each product (national bulk procurement, procurement through local distributors, or direct donation of product).

Step 4. Verify local and international pricing information for each presentation of each drug, for generic drugs, and for brand-name drugs.

Step 5. Identify any cost-recovery or cost-sharing mechanisms in effect. What is the cost of ARV drugs to patients (co-pay, free, sliding fee, partial subsidy)? How does (or how might) the cost to patients affect uptake, recruitment, and retention of patients on ART? This factor is likely to influence adherence rates.

Step 6. Identify any restrictions on financing regarding the types of drugs that can be procured (for example, funds from the Global Fund to Fight AIDS, Tuberculosis, and Malaria can be used to procure ARV drugs from WHO-prequalified suppliers, but PEPFAR funds can be used only to procure FDA-approved products).

Step 7. Verify flexibility in amounts and availability of funding (for example, are there potential funds that can be reallocated for procurement of ARV drugs and, if so, how long would reallocation take?).

For logistics data and supply chain information, these are the steps:

Step 1. Obtain national- and facility-level logistics data on ARV drug consumption, losses and adjustments, and stock on hand, if available.
Step 2. Calculate the expected wastage rate of ARV drug products because of loss or damage through normal handling or nonuse, that is, ARV drugs returned by patients that cannot be dispensed to another patient. In the absence of actual data, this expected wastage rate is currently assumed to be 5 percent until data from stock cards become available.

Step 3. Determine whether an inventory control system is in place for management of ARV drugs.

Step 4. Determine procurement lead times, supplier schedules, and lead times for delivery of product.

Step 5. Determine established buffer stock levels or maximum and minimum inventory levels, if available.

Step 6. Confirm facility order intervals.

Step 7. Determine the frequency and the timing of drug procurement procedures.

Determine the total number of patients on ART and the expected rates of change in patient treatment regimens within each forecast year as follows:

- Total number of existing patients (adult and pediatric) and the number of patients on each treatment regimen
- Estimated number of new patients who will initiate ART within each forecast year on standard first line regimen
- Phasing-in rate, or program expansion rate—the percentage of the total number of new patients who will have initiated ART by the end of each month or each quarter of the forecast year
- Of the number of patients on first line regimen (adults and children), the estimated percentages of patients who will experience side effects or toxicity to one of the three drugs or will become pregnant and need to switch to a single-drug substitute within the first line regimen (for example, severe anemia to ZDV, side effects to d4T, teratogenicity to EFV, or severe rash to NVP)
- Estimated percentage of patients who will experience treatment failure or will develop resistance to one or more of the three drugs in first line regimen and will require a complete regimen change to second line regimen
- Estimated percentage of patients on second line regimen who will experience side effects or toxicity to one of the three drugs and who will need to switch to a single-drug substitute within the second line regimen
- Estimated percentage of patients within each treatment regimen who will receive different doses of ARV drugs according to bodyweight (for example, d4T 30 mg if patient weight is less than 60 kg or d4T 40 mg if patient weight is more than 60 kg) and surface area (body weight and surface area measurements are needed to determine pediatric dosages)
- Estimated percentage of patients who are expected to be on concurrent TB and ART treatment who will require a change in ARV drug regimen

1 The estimated percentages of patients who will experience side effects or toxicity are specific for each drug and may also be country specific or program specific. Assumptions will need to be made about the length of time patients will be on a given treatment regimen before requiring a change in one, more than one, or all of the ARV drugs. For example, a certain percentage of patients will be expected to experience a severe skin rash from NVP within the initial two weeks of treatment when starting with a lead-in dose of 200 mg/day and will need to switch to EFV. Another percentage of patients will be expected to experience this severe skin rash and other toxicities related to NVP within the first six months of treatment, and yet others within the first 12 months of treatment. The timeframes within which specific ARV drug changes are expected to occur may be built into the forecast.
PREPARE FORECAST DEMAND

After one collects as much of the data and information as possible, one should prepare the forecast as follows:

- Document the assumptions that have been made on the basis of the data and the information collected and on the basis of input from ART stakeholders.
- Use either Excel spreadsheets or software that is designed to calculate the quantities of each ARV drug needed per day or per month—and then per year for each ARV drug regimen—and enter the number of patients estimated to be on each ARV drug regimen.
- Enter the expected rates of change within each treatment regimen (the percentage of patients who will need to make single-drug substitutions within each regimen because of side effects, toxicity, weight change, pregnancy, or HIV/TB co-infection, and the percentage of patients who will need to make a complete regimen change from first- to second line regimen because of treatment failure or drug resistance).
- Calculate the quantity of each ARV drug required per year to treat the estimated number of patients on each drug regimen and to adjust to changes in patient responses to treatment as previously noted. This total (presented as the total number of basic units required in its smallest unit) is the quantity required to meet the forecasted demand.

Appendix A, which is titled “Sample Excel Spreadsheets for Quantification of ARV Drugs,” provides an example of how to capture the assumptions for each step of the quantification and for how to complete calculations.

ADJUST THE FORECASTED DEMAND

In many environments where countries are still in the process of scaling up ART services, it is a useful step to crosscheck whether service delivery capacity is adequate to meet the identified patient targets. If service delivery capacity is still growing, the quantities of ARV drugs forecast to meet the expected demand should be further refined and adjusted, thereby taking into account the service delivery capacity. Factors to consider include the number of functioning ART sites, current volume of services, availability and skills of personnel, and existing laboratory infrastructure and capacity to support HIV diagnosis and patient monitoring for drug toxicities, treatment failure, or drug resistance.

An assessment of service delivery capacity will help determine (a) the greatest number of patients who can realistically initiate and continue treatment and (b) the appropriate quantities of product that can be used correctly to meet demand. Although service delivery capacity could actually exceed supply—in which case the quantities of ARV drugs required could be increased to treat more patients, given available funding—more commonly, the constraints in service delivery capacity can significantly reduce the number of patients who can be treated with quality ART services and, therefore, the quantities of ARV drugs that would be required. Any
changes in the forecasted demand because of capacity constraints should be agreed on through consultation and consensus with key stakeholders. At this point, the next step is to estimate the quantities of ARV drugs to order.

ESTIMATE REQUIREMENTS
At this step in the quantification, an assessment is needed of the supply status within the country to calculate the total quantity required of each ARV drug. The requirements estimate should be the amount that can reasonably be expected to be stored, distributed, and used before expiration. It should include the quantities of ARV drugs required to meet the forecasted demand and to fill the pipeline to ensure continuous supply at ART sites.

The requirements estimate must be adjusted for quantities already in the system (stock on hand) and quantities already ordered but not yet received (quantity on order) to meet desired stock levels. If one is to arrive at the requirements for the next one-year procurement period, adjustments need to be made to account for product wastage, lead time, buffer stock, stock on hand, and quantity on order. The requirements estimate may also need to be further adjusted to reflect storage and distribution capacity, especially for products that may require refrigeration.

The steps for estimating requirements consist of the following:

Step 1. Use Excel spreadsheets or software designed to calculate the quantity to order of each ARV drug, to arrive at the total quantity of each ARV drug needed for all uses of the drug (across the different treatment regimens) to treat the number of patients estimated to be on treatment for the next one-year period.

Step 2. Calculate the additional quantity of each ARV drug that will need to be ordered to cover the expected product wastage rate because of loss or damage through normal handling or nonuse (i.e., ARV drugs returned by patients that cannot be dispensed to other patients). ARV drug wastage rates are currently assumed to be 5 percent of the total forecasted demand until actual data become available from stock cards. The industry standard for wastage of essential medicines is 5 percent.

Step 3. Divide this wastage-adjusted total quantity required of each ARV drug by 12 to determine the average monthly quantity required (AMQR).

Step 4. For each ARV drug, multiply the AMQR by the number of months of buffer stock that will be required to cover the lead time. Lead time, expressed in months, should include the time required for preparing the quantification, for allocating and disbursing the funding, for contracting suppliers, for procuring the products, for delivering the shipment, for clearing customs, for inspecting the products, and for receiving the products into the central warehouse.

Step 5. Recalculate the total quantity required by adding the quantity of each drug required for buffer stock (from step 4) to the wastage-adjusted total quantity required (from step 3) so you get a new total quantity required for each drug. The new total quantity required includes adjustments for wastage and for quantities required to fill the pipeline.

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2 This step and step 4 in the next section can be completed using Excel spreadsheets, as described, or using DELIVER PipeLine software for procurement planning to determine quantities to order and the shipment delivery schedule. Visit the DELIVER website, http://www.deliver.jsi.com, to obtain the PipeLine software and the users’ manual.
Step 6. From this new quantity, subtract the total stock on hand of each ARV drug in the system on the last day of the month before the quantification was conducted. In the absence of reliable or complete data from all levels of the in-country supply chain, you may need to make assumptions about current stock levels. At the very least, you should deduct quantities of stock on hand at the central warehouse and at all intermediate warehouses and storage points.

Step 7. Finally, subtract the quantity on order of each ARV drug that may already have been procured and for which incoming shipments have not yet been received.

The resulting annual quantity to order is the quantity of each ARV drug needed to ensure full supply at ART sites for the year of the forecast.

See appendix A, “Sample Excel Spreadsheets for Quantification of ARV Drugs,” for an example of an Excel spreadsheet that was used to complete these calculations.

At some point during the quantification, additional adjustments in the requirements estimate may be necessary to adjust for the volume of product that can be adequately stored and distributed and to ensure the quality and security of the ARV drug supply. However, this adjustment does not always have to occur at this point; the adjustment can also take place during procurement planning and shipment scheduling. By using DELIVER’s ARV Drug Logistics Fact Sheets (DELIVER 2006) or other sources of information on packaging and shipment sizes of ARV drug products on the market, one may calculate the volume of incoming shipments and may compare it to actual storage space available in the country. The estimates of shipment volume and storage capacity are particularly important for products that may require refrigeration, such as Kaletra (LPV/r) and some pediatric formulations.

Consultants and stakeholders engaged in preparing the quantification are strongly advised to verify that adequate security measures exist for the volume of ARV drugs that are to be stored and distributed at the different levels of the program and at ART service sites as part of the quantification process. Adequate security measures reduce risk and minimize obstacles to distribution of ARV drug supplies once the products arrive in country.

If a maximum–minimum inventory control system has not been designed to ensure full supply of ARV drugs and if logistics data on stock on hand and on consumption of ARV drugs are not available at the time the quantification is conducted, you may need to make assumptions about (a) national and facility stock levels, (b) lead times for funding disbursement and procurement actions, (c) recommended buffer stocks, and (d) supplier delivery schedules and lead times.

**ESTIMATE COSTS**

Updated sources of information on generic and originator ARV drug prices, supplier rates, preferential pricing, and eligibility for pharmaceutical donation programs will be needed to estimate the cost of the quantities of ARV drugs to be ordered. In addition, information on the cost of insurance and freight, customs clearance and duties, and in-country storage and distribution may need to be added to the cost of the quantities of ARV drugs that are to be procured if that information is not included in supplier rates or budgeted for through other mechanisms or waiver agreements.
The steps for calculating the cost of the requirements are as follows:

Step 1. Using Excel spreadsheets or software that is designed to calculate the cost of the quantity to order of each ARV drug, enter the quantity to order as the total number of basic units of each drug (tablets, capsules, bottles of oral suspension) to be ordered for the year of the forecast.

Step 2. Enter the pack size for each ARV drug. The pack size is the number of basic units of the drug per smallest unit of supplier packaging (e.g., NVP 200 mg tablet, 60 tablets per bottle; AZT or ZDV 10 mg/mL syrup, 100 mL bottle).

Step 3. Adjust the quantity of the order by dividing the total number of basic units by pack size and rounding up the quantity of the order to the nearest whole unit of supplier packaging.

Step 4. Use the cost per pack as the unit of measure for calculating the total cost estimate of the ARV drugs to be ordered. Multiply the quantity to order of each ARV drug—rounded up to pack size—by the cost per pack to arrive at the total cost for the year of the forecast.

Step 5. If necessary, include other additional costs such as shipping, customs clearance, import taxes, etc. Those costs are often captured as an overall percentage of product costs. If local costs from past procurements have been used to calculate cost estimates, then ensure that the costs reflect only the price of products and do not include freight or other costs.

See appendix A, “Sample Excel Spreadsheets for Quantification of ARV Drugs,” for an example of an Excel spreadsheet that was used to complete these calculations.

Depending on the purpose of the quantification and the available sources of financing for procurement of ARV drugs, additional cost comparisons of generic against originator drugs or cost comparisons between suppliers may be required. The same Excel spreadsheet or software that was used to this point can also be used to create the comparison, by adding more columns for the different supplier rates and costs per pack so that alternate total cost scenarios can be determined.

DETERMINE QUANTITY TO PROCURE

The amount of funding available for procurement of ARV drugs is often a deciding factor when determining the final decision on the quantities to procure.

First, if sufficient funding is available, then the final quantity to procure of each ARV drug will be the same as the requirements estimate. In the current environment of increasing financial resources for ARV drug procurement, funding may be adequate to ensure full supply for a targeted number of patients for the period of the forecast, provided that service delivery and supply chain capacity exist. Financial resources could also surpass program capacity to expand quality ART services and to ensure a reliable and continuous supply of ARV drugs. In that case, additional quantities of ARV drugs should not be procured (even though the temptation may be to take advantage of available funding) because such procurement in excess of system capacities may result in loss of product through overstocking and expiration. As financial resources for ARV drug procurement increase, the challenge will be securing future sources of financing to continue procurement of ARVs for patients who are already on treatment and to expand ART services to reach more people.

Second, in situations where the cost estimate for procurement exceeds the available funding, an adjustment has to be made to the requirements estimate. The method for how this adjustment should be done will vary from country to country. However, a basic standard to uphold is that the priority for funding and procurement of
ARV drugs should be to maintain the ARV drug supply for patients already on ART. Quantities to procure must be sufficient to cover existing patients on ART. One option to ensure this supply is to reduce the number of patients who can be expected to initiate ART within the period of the forecast, therefore reducing the quantities of ARV drugs required.

The findings, methodology, and assumptions made in the quantification should be reviewed with ART stakeholders to reach a consensus on the reduced number of patients who will be expected to initiate treatment, given the restricted funding available for procurement of ARV drugs. Other options include maintaining advocacy efforts with other donors to fill the gap or—if there are restrictions on products that can be purchased by other donors—assigning a set of regimens to another donor to purchase. As an example, in Kenya, the PEPFAR program has committed to purchasing second line drugs for all patients enrolled on government-provided first line treatment who fail and then need second line treatment.

Third, in other situations, the purpose of the quantification may be to determine how many patients can be treated with ART for a year, given a specific amount of funding available. In that case, the cost of treating a specific number of cases of patients who are eligible for ART (e.g., cost per patient or cost per 1,000 cases) can be quantified for, and then matched against, available funding to determine the total number of patients who could initiate and continue ART for a year.

After the quantities to procure have been determined for the period of the forecast, a shipment schedule should be developed. Because of the uncertainties described previously, a flexible shipment schedule is recommended—often with quarterly shipments—in which shipment quantities can be adjusted to respond to uptake in services, changes in patient demand, existing stock levels, and rates of consumption of ARV drugs. Agreements with suppliers may also need to include flexibility in delaying shipments of the annual quantities procured into the year following the year of the forecast—if uptake of services does not meet expected demand.
CONSIDERATIONS FOR QUANTIFICATION OF PEDIATRIC ARV DRUGS

Forecasting demand for pediatric ART is even more complex than forecasting demand for adult ART. The level of detail required to forecast the quantities of pediatric ARV drugs needed for a specific number of patients reflects the general complexity and sophistication required for diagnosis, care, and treatment of pediatric ART patients.

Although the basic methodologies and approach described in this guide are used for quantification of pediatric ARV drugs, a number of key factors can influence and complicate the provision of pediatric ART services and the use of pediatric ARV drugs that must be addressed in the quantification. Those key factors include the following:

- Prescribing and dispensing of pediatric ARV drugs is complicated by the combined use of liquid, capsule, and tablet formulations.
- Formulations need to be changed and dosages need to be adjusted over time as the child grows.
- Adult ARV drug formulations are used for children and may need to be cut or crushed to meet pediatric dosing requirements.
- Patient adherence is difficult because of the complicated dosing, the large volumes, and the foul taste of liquid formulations, as well as the children’s inability to swallow pills.
- Selection and availability of ARV drug formulations for children are limited; for example, no fixed-dose combination drugs are currently approved for pediatric use, and the cost of pediatric formulations is relatively high.
- Most pediatric ARV formulations are bulky, liquid formulations that require additional storage space and refrigeration.
- Pediatric ARV drugs are not packaged according to dosing regimens, which complicates prescribing and dispensing.
- Pediatric doses are often reconstituted at service delivery levels and must be discarded after a certain period of time. The volume of use within that period of time is unpredictable and can vary from site to site.

The following additional steps must be incorporated into the quantification assumptions and calculations in order to estimate ARV drug requirements for children on ART. For an example of how those steps have been incorporated into a pediatric quantification, see appendix A, “Sample Excel Spreadsheets for Quantification of ARV Drugs,” which is attached to this guide.3

3 Appendix A illustrates a national quantification in which adult and pediatric ARV drug requirements have been incorporated into the forecasted demand and into the final estimate of requirements for procurement (in this example, pediatric liquid formulations have already been rounded up to bottle size).
Step 1. Calculate the number of pediatric patients who are expected to initiate ART during the period of the forecast. This number may be based on the number of children estimated to be on ART as a proportion of the total number of patients on ART for the forecast year. If data are available, the number may be based on an expected increase in the number of pediatric patients at ART sites in accordance with program expansion plans (e.g., plans to reach more mothers and children through expansion of PMTCT or new sites expected to initiate pediatric ART services within the forecast year).

Step 2. Apply a default rate to capture the number of pediatric patients who may discontinue treatment during the period of the forecast. Since experience in pediatric ART service provision is still relatively limited, this default rate is still heavily informed by assumptions.

Step 3. Apply a monthly or quarterly phasing-in rate to capture the gradual increase in the number of pediatric patients on ART over the period of the forecast.

Step 4. Verify and document the recommended pediatric dosages and formulations of each ARV drug by age and weight band.

Step 5. Categorize the existing and the estimated number of new pediatric patients on ART by age and weight band.

- The age grouping, which typically stratifies the under 3 year olds and children who are more than 3 years old, is made to be able to quantify liquid formulations for young children who are not yet able to swallow tablets or capsules, and to avoid the use of Efavirenz, which is contraindicated in children under 3 years of age.

Step 6. Calculate the number of basic units (tablet, capsule, or milliliters of liquid) of each ARV drug required per day for each patient within each of the weight band or body surface area measurement groups.

- Liquid formulations must be calculated in milliliters (mL) at this point to determine the number of basic units required per patient per day.

- The quantities of liquid formulations required are then converted to supplier packaging sizes for procurement later in the quantification (e.g., 100 mL, 200 mL, or 240 mL bottles).

Step 7. Calculate the adjusted dosages of the adult ARV drug formulations that will be used for children (e.g., one-half tablet of AZT 300 mg/3TC 150 mg; use of EFV 50 mg capsules).

Step 8. Multiply the basic number of units of each ARV drug product required per day by the total number of patient-days for each forecast year.

Step 9. Add the total quantity required of each ARV drug product across all measurement groups organized by age and weight band for each forecast year.

Step 10. Calculate a wastage rate for the pediatric formulations. A separate wastage rate may need to be applied for liquid formulations, which have a much higher wastage rate because of their large volume and short shelf life. If data are available, then wastage rates can be estimated on the basis of a ratio of the quantities of products dispensed to the quantities of product expired over the total stock quantity. In the absence of country-specific information, wastage rates of between 5 and 15 percent can be
used, or another wastage rate may be used that has been otherwise agreed upon in consultation with informed stakeholders.

Step 11. Calculate the storage space required for refrigerated transport and storage of pediatric formulations. The logistics implications of storing and distributing the quantities of pediatric formulations that will be procured must be taken into account in the quantification. The available refrigerated storage space in-country should be calculated and compared with the storage space required for the volume of incoming shipments of pediatric formulations that will require maintenance of the cold chain in storage and transport.
USE OF PIPELINE SOFTWARE FOR QUANTIFICATION AND PROCUREMENT PLANNING OF ARV DRUGS

Although all the previous steps have been described on the basis of using an Excel spreadsheet to capture all the assumptions and to perform all the calculations in the quantification process, a growing number of quantification software packages are available to assist with the process. As of the publication date of this guide, however, none of the available software packages reviewed are able to capture all the steps outlined in this quantification guide. However, individual software does capture part of the process and would be useful if complemented by other software packages. For example, the Partnership for Supply Chain Management project is exploring the combined use of Quantimed and PipeLine software to conduct ARV drug quantification.

As an alternative to using an Excel spreadsheet for the entire process, DELIVER is moving toward the use of Excel to produce the forecast demand, followed by the use of PipeLine to complete the quantification and to enable procurement planning as well. There are several benefits to this approach, including the fact that PipeLine can be used to plan and adjust shipment quantities and delivery schedules and to help identify funding needs for procurement. PipeLine is also a useful tool for sharing results among stakeholders, because it produces reports and graphs on the status of scheduled shipments, of past and projected consumption trends, and of stock levels for each product in-country.

Preparing a quantification using a combination of Excel spreadsheets and PipeLine software includes the following steps:

Step 1. Once the forecasted demand for each ARV drug product has been estimated (presented as the total number of basic units required in its smallest unit, such as tablets, capsules, or bottles), those figures can be entered directly into the PipeLine software as forecasted consumption by forecast year.

Step 2. Additional program, background, and commodities data will need to be entered in order to finalize the requirements estimate.

Step 3. Producing the cost estimate and shipment schedules for procurement in PipeLine will require entry of information on the sources of funding, suppliers, packaging size, and product and shipping costs, as well as entry of logistics information on supplier lead times, desired stock levels, and stock on hand.

Because the forecasted demand data from Excel spreadsheets will have to be entered manually into PipeLine, all forecasting assumptions and calculations should be finalized before transferring data to PipeLine to ensure that—once data entry has been completed—it will be unnecessary to re-enter the whole dataset should there be a change in the forecasted demand.

4 The DELIVER staff has worked in conjunction with staff members from Management Sciences for Health (MSH) and the Clinton Foundation to use tools developed by each of those organizations for ARV drug quantification. MSH’s tool, Quantimed, is a general tool for quantifying essential medicines that can be used for ARV drugs, and the Clinton Foundation has also developed a useful Excel-based tool.

5 PipeLine is a software package available from the DELIVER project. Visit www.deliverjsi.com to download a free copy of the software and the users’ manual.
SUMMARY OF CHALLENGES AND LESSONS LEARNED IN QUANTIFICATION OF ARV DRUGS

COMMON CHALLENGES
While preparing national-level ARV drug quantifications in eight countries, DELIVER identified a number of challenges that were common and consistent across the different countries. The challenges are summarized next and were the key guiding principles in developing the approach to quantification presented in this guide.

• Data on ART services and ARV drug supply are limited and, when available, are often unreliable or insufficient to be used for quantifying ARV drug requirements.

• Standard treatment guidelines may be inconsistent, may need revision, or may not have been widely disseminated to providers.

• Program targets may not take into account either the service delivery capacity to increase enrollment of new patients and to continue monitoring existing patients on ART or the supply chain capacity to finance, procure, and manage greater volumes of ARV drugs.

• Program expansion does not occur as rapidly as expected.

• Multiple sources of funding, procurement mechanisms, and distribution channels are used for ARV drugs.

• Quantification capacity is limited at the country and program levels.

• Communication and coordination are lacking among key stakeholders and implementers (i.e., policymakers, program managers, service providers, funding sources, procurement agents, and suppliers) on issues related to the selection, quantification, and procurement of ARV drug needs.

• Quantification and procurement often occur when funding becomes available, rather than as a program planning activity that identifies commodity needs and that mobilizes resources for procurement in a timely fashion. Quantification and procurement that occur when funding becomes available have led to stockouts and to expensive emergency procurements.

• Worldwide shortages of raw materials for the manufacture of ARV drugs and other limitations in supplier production capacity may need to be addressed in the quantification to identify alternate sources of supply for the required quantities of a product.

USEFUL LESSONS
The following lessons that have been learned from DELIVER’s experience in conducting ARV drug quantifications in eight countries have also been incorporated into the approach to quantification that is presented in this guide.
• The quantification exercise itself is time intensive and resource intensive. Therefore, adequate time, funding, and human resources with appropriate skills to conduct the quantification exercise should be planned and should be included in the budget.

• Quantifications that currently are based on informed assumptions will become more evidence-based over time as the availability and quality of data improve through the strengthening of the LMIS.

• Quantification requires a consultative process with multiple stakeholders and implementers to inform the assumptions about the selection, quantification, and procurement of ARV drugs.

• Convening one or more consultative stakeholder meetings throughout the quantification process is recommended to clarify and review the data sources, assumptions, and methodologies used, and to reach consensus on commodity requirements and funding needs. Consultative stakeholder meetings can be a critical step toward transferring ownership of the results to in-country stakeholders. The meetings can also serve to facilitate resource mobilization, clarify expectations, and promote collaboration and coordination, especially in the event of disruptions in commodity supply that may affect availability of products for customers at service delivery points.

• The quantification should be based on realistic program plans and on available financing.

• The results of the quantification should be used to determine specific order quantities and shipment schedules for short-term procurement planning on the basis of available funding.

• The results of the quantification should also be used for medium- and long-term program planning and for resource mobilization for ART.

• The quantification should be reviewed and updated at least every six months, and procurement plans should be adjusted accordingly.
REFERENCES


## APPENDIX A

SAMPLE EXCEL SPREADSHEETS FOR QUANTIFICATION OF ARV DRUGS

### PATIENT TARGETS

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<th>Assumptions</th>
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<th>2005</th>
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<td>Adult AIDS cases eligible for and accessing ART</td>
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**TOTAL TARGETS FOR TREATMENT**

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### TOTAL PATIENTS 2005

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<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td># Adults on 1st Line Regimens</td>
<td>22,563</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># Adults on 2nd Line Regimens</td>
<td>1,188</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># Children on 1st Line Regimens</td>
<td>1,188</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># Children on 2nd Line Regimens</td>
<td>63</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># HIV positive mothers on PMTCT</td>
<td>46,000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># Infants on PMTCT</td>
<td></td>
<td>46,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td># PMTCT mothers on NVP/labor</td>
<td></td>
<td>46,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td># PMTCT mothers on AZT</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># PMTCT infants</td>
<td></td>
<td>46,000</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## TOTAL PATIENTS 2006

<table>
<thead>
<tr>
<th>Total No. Patients</th>
<th>45,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent on 1st Line Regimens</td>
<td>93%</td>
</tr>
<tr>
<td>Percent on 2nd Line Regimens</td>
<td>7%</td>
</tr>
<tr>
<td>Percent Adults</td>
<td>95%</td>
</tr>
<tr>
<td>Percent Children</td>
<td>5%</td>
</tr>
</tbody>
</table>

| # Adults on 1st Line Regimens | 39,758 |
| # Adults on 2nd Line Regimens | 2,993 |
| # Children on 1st Line Regimens | 2,093 |
| # Children on 2nd Line Regimens | 158 |

| # HIV positive mothers on PMTCT | 56,000 |
| # Infants on PMTCT | 56,000 |

| # PMTCT mothers on NVP/labor | 28,000 |
| # PMTCT mothers on AZT | 28,000 |
| # PMTCT infants | 56,000 |

## TOTAL PATIENTS 2007

<table>
<thead>
<tr>
<th>Total No. Patients</th>
<th>100,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent on 1st Line Regimens</td>
<td>90%</td>
</tr>
<tr>
<td>Percent on 2nd Line Regimens</td>
<td>10%</td>
</tr>
<tr>
<td>Percent Adults</td>
<td>90%</td>
</tr>
<tr>
<td>Percent Children</td>
<td>10%</td>
</tr>
</tbody>
</table>

| # Adults on 1st Line Regimens | 81,000 |
| # Adults on 2nd Line Regimens | 9,000 |
| # Children on 1st Line Regimens | 9,000 |
| # Children on 2nd Line Regimens | 1,000 |

| # HIV positive mothers on PMTCT | 76,000 |
| # Infants on PMTCT | 76,000 |

| # PMTCT mothers on NVP/labor | 38,000 |
| # PMTCT mothers on AZT | 38,000 |
| # PMTCT infants | 76,000 |

<table>
<thead>
<tr>
<th>PMTCT</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>New ANC attendees</td>
<td>9,403</td>
<td>10,000</td>
<td>15,000</td>
<td>20,000</td>
</tr>
<tr>
<td>Pregnant women tested (%)</td>
<td>30%</td>
<td>50%</td>
<td>75%</td>
<td>95%</td>
</tr>
<tr>
<td># Pregnant women tested</td>
<td>2,821</td>
<td>5,000</td>
<td>11,250</td>
<td>19,000</td>
</tr>
<tr>
<td># Pregnant women positive (eligible for prophylaxis)</td>
<td>451</td>
<td>800</td>
<td>1,800</td>
<td>3,040</td>
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</tbody>
</table>
### YEAR 2005

<table>
<thead>
<tr>
<th></th>
<th>Percent</th>
<th>No. Patients</th>
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</thead>
<tbody>
<tr>
<td>Total No. Patients</td>
<td>100%</td>
<td>25,000</td>
</tr>
<tr>
<td>Percent on 1st Line Regimen</td>
<td>95%</td>
<td>22,563</td>
</tr>
<tr>
<td>Percent on 2nd Line Regimen</td>
<td>5%</td>
<td>1,188</td>
</tr>
<tr>
<td>Percent Adults</td>
<td>95%</td>
<td>23,750</td>
</tr>
<tr>
<td>Percent Children</td>
<td>5%</td>
<td>1,250</td>
</tr>
</tbody>
</table>

### 1st Line Regimens (Adults)

<table>
<thead>
<tr>
<th>Option</th>
<th>1st Line Regimens (Adults)</th>
<th>Percent</th>
<th>No. Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1</td>
<td>d4T (30mg)/3TC/NVP</td>
<td>25%</td>
<td>5,641</td>
</tr>
<tr>
<td>A2</td>
<td>d4T (40mg)/3TC/NVP</td>
<td>20%</td>
<td>4,513</td>
</tr>
<tr>
<td>B</td>
<td>(AZT/3TC+NVP) Aspen co-pack</td>
<td>42%</td>
<td>9,476</td>
</tr>
<tr>
<td>C1</td>
<td>d4T (30mg)/3TC+EFV</td>
<td>5%</td>
<td>1,128</td>
</tr>
<tr>
<td>C2</td>
<td>d4T (40mg)/3TC+EFV</td>
<td>5%</td>
<td>1,128</td>
</tr>
<tr>
<td>D</td>
<td>AZT/3TC+EFV</td>
<td>3%</td>
<td>677</td>
</tr>
</tbody>
</table>

### 2nd Line Regimens (Adults)

<table>
<thead>
<tr>
<th>Option</th>
<th>2nd Line Regimens (Adults)</th>
<th>Percent</th>
<th>No. Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>E1</td>
<td>TDF + ddI + LPV/r &lt; 60kg</td>
<td>23%</td>
<td>273</td>
</tr>
<tr>
<td>E2</td>
<td>TDF + ddI + LPV/r &gt; 60kg</td>
<td>23%</td>
<td>273</td>
</tr>
<tr>
<td>F1</td>
<td>TDF + ddI + NFV &lt; 60kg</td>
<td>23%</td>
<td>273</td>
</tr>
<tr>
<td>F2</td>
<td>TDF + ddI + NFV &gt; 60kg</td>
<td>23%</td>
<td>273</td>
</tr>
<tr>
<td>G1</td>
<td>ABC + ddI + LPV/r &lt; 60kg</td>
<td>1%</td>
<td>12</td>
</tr>
<tr>
<td>G2</td>
<td>ABC + ddI + LPV/r &gt;60kg</td>
<td>1%</td>
<td>12</td>
</tr>
<tr>
<td>H1</td>
<td>TDF + ddI + SQV + r &lt; 60kg</td>
<td>3.0%</td>
<td>36</td>
</tr>
<tr>
<td>H2</td>
<td>TDF + ddI + SQV + r &gt; 60kg</td>
<td>3.0%</td>
<td>36</td>
</tr>
</tbody>
</table>

### PMTCT Prophylaxis (Mother)

<table>
<thead>
<tr>
<th>Option</th>
<th>PMTCT Prophylaxis (Mother)</th>
<th>Percent</th>
<th>No. Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>M</td>
<td>AZT 300mg bd/6 weeks</td>
<td>0%</td>
<td>0</td>
</tr>
<tr>
<td>N</td>
<td>NVP 200mg at labor</td>
<td>100%</td>
<td>46,000</td>
</tr>
</tbody>
</table>
### 1ST LINE REGIMENS

<table>
<thead>
<tr>
<th>Phasing-In by %</th>
<th>%</th>
<th># Days</th>
<th>Patients</th>
<th>Patient-days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quarter 1</td>
<td>15%</td>
<td>365</td>
<td>3,384.38</td>
<td>1,235,297</td>
</tr>
<tr>
<td>Quarter 2</td>
<td>20%</td>
<td>275</td>
<td>4,512.50</td>
<td>1,240,938</td>
</tr>
<tr>
<td>Quarter 3</td>
<td>30%</td>
<td>184</td>
<td>6,768.75</td>
<td>1,245,450</td>
</tr>
<tr>
<td>Quarter 4</td>
<td>35%</td>
<td>92</td>
<td>7,896.88</td>
<td>726,513</td>
</tr>
<tr>
<td><strong>100%</strong></td>
<td></td>
<td></td>
<td><strong>22,563</strong></td>
<td></td>
</tr>
</tbody>
</table>

Total patient-days covered: 4,448,197
Total possible patient-days: 8,235,313
% total patient-days covered: 54.01%

### 2ND LINE REGIMENS

<table>
<thead>
<tr>
<th>Phasing-In by %</th>
<th>%</th>
<th># Days</th>
<th>Patients</th>
<th>Patient-days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quarter 1</td>
<td>5%</td>
<td>365</td>
<td>59.38</td>
<td>21,672</td>
</tr>
<tr>
<td>Quarter 2</td>
<td>10%</td>
<td>275</td>
<td>118.75</td>
<td>32,656</td>
</tr>
<tr>
<td>Quarter 3</td>
<td>25%</td>
<td>184</td>
<td>296.88</td>
<td>54,625</td>
</tr>
<tr>
<td>Quarter 4</td>
<td>60%</td>
<td>92</td>
<td>713</td>
<td>65,550</td>
</tr>
<tr>
<td><strong>100%</strong></td>
<td></td>
<td></td>
<td><strong>1,188</strong></td>
<td></td>
</tr>
</tbody>
</table>

Total patient-days covered: 174,503
Total possible patient-days: 433,438
% total patient-days covered: 40.26%
## ADULT REGIMENS YEAR 2006

### YEAR 2006

<table>
<thead>
<tr>
<th></th>
<th>Percent</th>
<th>No. Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total No. Patients</td>
<td>100%</td>
<td>45,000</td>
</tr>
<tr>
<td>Percent on 1st Line Regimen</td>
<td>93%</td>
<td>39,758</td>
</tr>
<tr>
<td>Percent on 2nd Line Regimen</td>
<td>7%</td>
<td>2,993</td>
</tr>
<tr>
<td>Percent Adults</td>
<td>95%</td>
<td>42,750</td>
</tr>
<tr>
<td>Percent Children</td>
<td>5%</td>
<td>2,250</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Option</th>
<th>1st Line Regimens (Adults)</th>
<th>Percent</th>
<th>No. Patients</th>
<th>New Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total No. Patients</td>
<td>100%</td>
<td>39,758</td>
<td></td>
</tr>
<tr>
<td>A1</td>
<td>d4T (30mg)/3TC/NVP</td>
<td>28%</td>
<td>11,132</td>
<td>5,491</td>
</tr>
<tr>
<td>A2</td>
<td>d4T (40mg)/3TC/NVP</td>
<td>25%</td>
<td>9,939</td>
<td>5,427</td>
</tr>
<tr>
<td>B</td>
<td>(AZT/3TC+NVP) Aspen co-pack</td>
<td>34%</td>
<td>13,518</td>
<td>4,041</td>
</tr>
<tr>
<td>C1</td>
<td>d4t (30mg)/3TC+EFV</td>
<td>5%</td>
<td>1,988</td>
<td>860</td>
</tr>
<tr>
<td>C2</td>
<td>d4t (40mg)/3TC+EFV</td>
<td>5%</td>
<td>1,988</td>
<td>860</td>
</tr>
<tr>
<td>D</td>
<td>AZT/3TC+EFV</td>
<td>3%</td>
<td>1,193</td>
<td>516</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Option</th>
<th>2nd Line Regimens (Adults)</th>
<th>Percent</th>
<th>No. Patients</th>
<th>New Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total No. Patients</td>
<td>100%</td>
<td>2,993</td>
<td></td>
</tr>
<tr>
<td>E1</td>
<td>TDF + dd1 + LPV/r &lt; 60kg</td>
<td>23%</td>
<td>688</td>
<td>415</td>
</tr>
<tr>
<td>E2</td>
<td>TDF + dd1 + LPV/r &gt; 60kg</td>
<td>25%</td>
<td>748</td>
<td>475</td>
</tr>
<tr>
<td>F1</td>
<td>TDF + dd1 + NFV &lt; 60kg</td>
<td>23%</td>
<td>688</td>
<td>415</td>
</tr>
<tr>
<td>F2</td>
<td>TDF + dd1 + NFV &gt; 60kg</td>
<td>25%</td>
<td>748</td>
<td>475</td>
</tr>
<tr>
<td>G1</td>
<td>ABC + dd1 + LPV/r &lt; 60kg</td>
<td>1%</td>
<td>15</td>
<td>3</td>
</tr>
<tr>
<td>G2</td>
<td>ABC + dd1 + LPV/r &gt; 60kg</td>
<td>1%</td>
<td>15</td>
<td>3</td>
</tr>
<tr>
<td>H1</td>
<td>TDF + dd1 + SQV + r &lt; 60kg</td>
<td>1.5%</td>
<td>45</td>
<td>9</td>
</tr>
<tr>
<td>H2</td>
<td>TDF + dd1 + SQV + r &gt; 60kg</td>
<td>1.5%</td>
<td>45</td>
<td>9</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Option</th>
<th>PMTCT Prophylaxis</th>
<th>Percent</th>
<th>No. Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>M</td>
<td>AZT 300mg bd/6 weeks</td>
<td>50%</td>
<td>28,000</td>
</tr>
<tr>
<td>N</td>
<td>NVP 200mg at labor</td>
<td>50%</td>
<td>28,000</td>
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</table>
### ADULT REGIMENS YEAR 2006

#### PHASING-IN RATES

<table>
<thead>
<tr>
<th>1st LINE REGIMENS</th>
<th>Existing Pts (Year 2005)</th>
<th>New Pts</th>
<th>Total New (New + Default)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phasing-in 1st Line Regimens</td>
<td>22,563</td>
<td>17,195</td>
<td>18,323</td>
</tr>
<tr>
<td>Default Rate 1st Line Regimens</td>
<td>5%</td>
<td>1,128</td>
<td></td>
</tr>
</tbody>
</table>

#### PHASING-IN OF NEW PATIENTS ON 1ST LINE REGIMENS

<table>
<thead>
<tr>
<th>Phasing-In by %</th>
<th>%</th>
<th># Days</th>
<th>Patients</th>
<th>Patient-days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quarter 1</td>
<td>25%</td>
<td>365</td>
<td>4,581</td>
<td>1,671,985</td>
</tr>
<tr>
<td>Quarter 2</td>
<td>25%</td>
<td>275</td>
<td>4,581</td>
<td>1,259,715</td>
</tr>
<tr>
<td>Quarter 3</td>
<td>25%</td>
<td>184</td>
<td>4,581</td>
<td>842,864</td>
</tr>
<tr>
<td>Quarter 4</td>
<td>25%</td>
<td>92</td>
<td>4,581</td>
<td>421,432</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td>18,323</td>
<td>4,195,996</td>
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#### 2nd LINE REGIMENS

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Default Rate 2nd Line Regimens</td>
<td>1,188</td>
<td>1,805</td>
<td>1,864</td>
</tr>
<tr>
<td>5%</td>
<td>59</td>
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#### PHASING-IN OF NEW PATIENTS ON 2ND LINE REGIMENS

<table>
<thead>
<tr>
<th>Phasing In by %</th>
<th>%</th>
<th># Days</th>
<th>Patients</th>
<th>Patient-days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quarter 1</td>
<td>15%</td>
<td>365</td>
<td>280</td>
<td>102,075</td>
</tr>
<tr>
<td>Quarter 2</td>
<td>20%</td>
<td>275</td>
<td>373</td>
<td>102,541</td>
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<tr>
<td>Quarter 3</td>
<td>30%</td>
<td>184</td>
<td>559</td>
<td>102,914</td>
</tr>
<tr>
<td>Quarter 4</td>
<td>35%</td>
<td>92</td>
<td>653</td>
<td>60,033</td>
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<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td>1,864</td>
<td>367,562</td>
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#### PMTCT Prophylaxis

<table>
<thead>
<tr>
<th>No. Patients</th>
<th>Patient-days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total No. Patients</td>
<td>100%</td>
</tr>
<tr>
<td>AZT 300mg bid/ 6 weeks</td>
<td>50%</td>
</tr>
<tr>
<td>NVP 200mg at labor</td>
<td>50%</td>
</tr>
</tbody>
</table>
## ADULT REGIMENS YEAR 2007

<table>
<thead>
<tr>
<th>YEAR 2007</th>
<th>Percent</th>
<th>No. Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total No. Patients</td>
<td>100%</td>
<td>100,000</td>
</tr>
<tr>
<td>Percent on 1st Line Regimen</td>
<td>90%</td>
<td>81,000</td>
</tr>
<tr>
<td>Percent on 2nd Line Regimen</td>
<td>10%</td>
<td>9,000</td>
</tr>
<tr>
<td>Percent Adults</td>
<td>90%</td>
<td>90,000</td>
</tr>
<tr>
<td>Percent Children</td>
<td>10%</td>
<td>10,000</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Option</th>
<th>1st Line Regimens (Adults)</th>
<th>Percent</th>
<th>No. Patients</th>
<th>New Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total No. Patients</td>
<td>100%</td>
<td>81,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A1</td>
<td>d4T (30mg)/3TC/NVP</td>
<td>28%</td>
<td>22,680</td>
<td>11,548</td>
</tr>
<tr>
<td>A2</td>
<td>d4T (40mg)/3TC/NVP</td>
<td>29%</td>
<td>23,490</td>
<td>13,551</td>
</tr>
<tr>
<td>B</td>
<td>(AZT/3TC+NVP) Aspen co-pack</td>
<td>30%</td>
<td>24,300</td>
<td>10,782</td>
</tr>
<tr>
<td>C1</td>
<td>d4T (30mg)/3TC+EFV</td>
<td>5%</td>
<td>4,050</td>
<td>2,062</td>
</tr>
<tr>
<td>C2</td>
<td>d4T (40mg)/3TC+EFV</td>
<td>5%</td>
<td>4,050</td>
<td>2,062</td>
</tr>
<tr>
<td>D</td>
<td>AZT/3TC+EFV</td>
<td>3%</td>
<td>2,430</td>
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<table>
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<th>Option</th>
<th>2nd Line Regimens (Adults)</th>
<th>Percent</th>
<th>No. Patients</th>
<th>New Patients</th>
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<td>Total No. Patients</td>
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<tr>
<td>E1</td>
<td>TDF + ddl + LPV/r &lt; 60kg</td>
<td>23%</td>
<td>2,070</td>
<td>1,382</td>
</tr>
<tr>
<td>E2</td>
<td>TDF + ddl + LPV/r &gt; 60kg</td>
<td>26%</td>
<td>2,340</td>
<td>1,592</td>
</tr>
<tr>
<td>F1</td>
<td>TDF + ddl + NFV &lt; 60kg</td>
<td>23%</td>
<td>2,070</td>
<td>1,382</td>
</tr>
<tr>
<td>F2</td>
<td>TDF + ddl + NFV &gt; 60kg</td>
<td>26%</td>
<td>2,340</td>
<td>1,592</td>
</tr>
<tr>
<td>G1</td>
<td>ABC + ddl + LPV/r &lt; 60kg</td>
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<td>30</td>
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<td>G2</td>
<td>ABC + ddl + LPV/r &gt;60kg</td>
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<td>30</td>
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<td>TDF + ddl + SQV + r &lt; 60kg</td>
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<td>45</td>
<td>0</td>
</tr>
<tr>
<td>H2</td>
<td>TDF + ddl + SQV + r &gt; 60kg</td>
<td>0.5%</td>
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<table>
<thead>
<tr>
<th>Option</th>
<th>PMTCT Prophylaxis</th>
<th>Percent</th>
<th>No. Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>M</td>
<td>AZT 300mg bd/6 weeks (42 days)</td>
<td>100%</td>
<td>76,000</td>
</tr>
<tr>
<td>N</td>
<td>NVP 200 mg at labour</td>
<td>50%</td>
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### ADULT REGIMENS YEAR 2007

#### PHASING-IN RATES

<table>
<thead>
<tr>
<th>1st LINE REGIMENS</th>
<th>Percent</th>
<th>Existing Pts (Year 2006)</th>
<th>New Patients</th>
<th>Total New (New + Default)</th>
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</thead>
<tbody>
<tr>
<td>Phasing-in 1st Line</td>
<td>5%</td>
<td>39,758</td>
<td>41,243</td>
<td>43,230</td>
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<tr>
<td>Default Rate 1st Line</td>
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<td>1,988</td>
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#### PHASING-IN OF NEW PATIENTS ON 1ST LINE REGIMENS

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<th>Phasing In by %</th>
<th>%</th>
<th># days</th>
<th>Patients</th>
<th>Patient-days</th>
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<tbody>
<tr>
<td>Quarter 1</td>
<td>25%</td>
<td>365</td>
<td>10,808</td>
<td>3,944,772</td>
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<tr>
<td>Quarter 2</td>
<td>25%</td>
<td>275</td>
<td>10,808</td>
<td>2,972,088</td>
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<tr>
<td>Quarter 3</td>
<td>25%</td>
<td>184</td>
<td>10,808</td>
<td>1,988,597</td>
</tr>
<tr>
<td>Quarter 4</td>
<td>25%</td>
<td>92</td>
<td>10,808</td>
<td>994,299</td>
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<td>Total</td>
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#### 2nd LINE REGIMENS

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<th>Percent</th>
<th>Existing Pts (Year 2006)</th>
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<th>Total New (New + Default)</th>
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<tr>
<td>Phasing-in 2nd Line</td>
<td>5%</td>
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<td>6,008</td>
<td>6,157</td>
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<tr>
<td>Default Rate 2nd Line</td>
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#### PHASING-IN OF NEW PATIENTS ON 2ND LINE REGIMENS

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<th>Phasing In by %</th>
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<th>Patient-days</th>
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<tr>
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<td>15%</td>
<td>365</td>
<td>924</td>
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<td>Quarter 2</td>
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<tr>
<td>Quarter 3</td>
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#### PMTCT Prophylaxis

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<tr>
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<th>%</th>
<th># Days</th>
<th>No. Patients</th>
<th>Patient-days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total No. Patients</td>
<td></td>
<td></td>
<td>76,000</td>
<td></td>
</tr>
<tr>
<td>AZT 300mg bd X 6 weeks (42 days)</td>
<td>50%</td>
<td>42</td>
<td>38,000</td>
<td>1,596,000</td>
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<tr>
<td>NVP 200mg at labor</td>
<td>50%</td>
<td>1</td>
<td>38,000</td>
<td>38,000</td>
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</table>

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**Note:** The document details the phasing-in rates and numbers of new patients for both 1st and 2nd line antiretroviral (ARV) regimens, as well as PMTCT (Pediatric Morbidity and Mortality Prevention) prophylaxis. The tables provide percentages, the number of days, and the total patient-days for each phase and regimen.
### QUALITY REQUIRED (ADULTS)  
#### FORECAST YEARS 2005–2007

<table>
<thead>
<tr>
<th>Option</th>
<th>REGIMENS</th>
<th>YEAR 2005</th>
<th>YEAR 2006</th>
<th>YEAR 2007</th>
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<tbody>
<tr>
<td></td>
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<td>No. Patients</td>
<td>Units per Patient-days</td>
<td>No. Basic Units Required</td>
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<tr>
<td>1st Line Regimens (Adults)</td>
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<td></td>
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<tr>
<td>A1</td>
<td>d4T (30mg)+3TC+NVP</td>
<td>5,641</td>
<td>1,112,049</td>
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<td>3TC/d4T (30)</td>
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<td>NVP 200mg</td>
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</tr>
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<tr>
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<tr>
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<td>222,410</td>
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</tr>
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<tr>
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<td>d4T (40)/3TC</td>
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## QUALITY REQUIRED (ADULTS)  FORECAST YEARS 2005–2007 (CONTINUED)

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<th>Patients-days</th>
<th>Units per Patient-day</th>
<th>No. Basic Units Required</th>
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<tr>
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<td>40,136</td>
<td>688</td>
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<td>181,537</td>
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<td>529,914</td>
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<td>1</td>
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<td>529,914</td>
<td>1</td>
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<tr>
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<td>ddI 25mg</td>
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<td>363,075</td>
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<tr>
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<tr>
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<tr>
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<td>386,674</td>
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### Quality Required (Adults) Forecast Years 2005–2007 (Continued)

<table>
<thead>
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<th>Option</th>
<th>Regimens</th>
<th>No. Patients</th>
<th>Patient-days</th>
<th>Units per Patient-day</th>
<th>No. Basic Units Required</th>
<th>Year 2005</th>
<th>Year 2006</th>
<th>Year 2007</th>
</tr>
</thead>
<tbody>
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<td>16,425</td>
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<td>16,425</td>
<td>16,425</td>
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<tr>
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<td>ddI 200mg</td>
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<td>1,745</td>
<td>1</td>
<td>16,425</td>
<td>1</td>
<td>16,425</td>
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<tr>
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<td>16,425</td>
<td>10</td>
<td>16,425</td>
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<tr>
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<td>16,425</td>
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<td>10,470</td>
<td>2</td>
<td>32,768</td>
<td>2</td>
<td>32,768</td>
<td>32,768</td>
</tr>
<tr>
<td></td>
<td>SQV 200mg</td>
<td>10</td>
<td>52,351</td>
<td>10</td>
<td>163,839</td>
<td>10</td>
<td>164,250</td>
<td>164,250</td>
</tr>
<tr>
<td></td>
<td>r (Ritonavir) 100mg</td>
<td>2</td>
<td>10,470</td>
<td>2</td>
<td>32,768</td>
<td>2</td>
<td>32,768</td>
<td>32,768</td>
</tr>
<tr>
<td>&gt; 60 kg</td>
<td>TDF 300mg</td>
<td>36</td>
<td>5,235</td>
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<td>10,470</td>
<td>2</td>
<td>10,470</td>
<td>10,470</td>
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<tr>
<td></td>
<td>ddI 200mg</td>
<td>2</td>
<td>10,470</td>
<td>2</td>
<td>32,768</td>
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<td>32,768</td>
<td>32,768</td>
</tr>
<tr>
<td></td>
<td>SQV 200mg</td>
<td>10</td>
<td>52,351</td>
<td>10</td>
<td>163,839</td>
<td>10</td>
<td>164,250</td>
<td>164,250</td>
</tr>
<tr>
<td></td>
<td>r (Ritonavir) 100mg</td>
<td>2</td>
<td>10,470</td>
<td>2</td>
<td>32,768</td>
<td>2</td>
<td>32,768</td>
<td>32,768</td>
</tr>
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<td>PMTCT Prophylaxis 46,000</td>
<td>AZT 300mg</td>
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<td>2,352,000</td>
<td>2</td>
<td>3,192,000</td>
<td>3,192,000</td>
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<tr>
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<td>2</td>
<td>28,000</td>
<td>2</td>
<td>28,000</td>
<td>28,000</td>
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</table>

**Appendix A 45**
<table>
<thead>
<tr>
<th>Option</th>
<th>1st Line Regimens (Children)</th>
<th>Percent</th>
<th>No. Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total No. Patients</td>
<td>100%</td>
<td>1,188</td>
</tr>
<tr>
<td></td>
<td>Percentage under 3 years, &lt;12kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P1</td>
<td>AZT+3TC+NVP</td>
<td>50%</td>
<td>416</td>
</tr>
<tr>
<td>P2</td>
<td>d4T+3TC+NVP</td>
<td>50%</td>
<td>416</td>
</tr>
<tr>
<td></td>
<td>Percentage &gt;3-12 yrs, 12-30kgs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P3</td>
<td>(AZT/3TC+NVP) Aspen co-pack</td>
<td>60%</td>
<td>214</td>
</tr>
<tr>
<td>P4</td>
<td>d4T30/3TC/NVP</td>
<td>20%</td>
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</tr>
<tr>
<td>P5</td>
<td>d4T30/3TC+EFV</td>
<td>20%</td>
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<table>
<thead>
<tr>
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<th>2nd Line Regimens (Children)</th>
<th>Percent</th>
<th>No. Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total No. Patients</td>
<td>100%</td>
<td>63</td>
</tr>
<tr>
<td></td>
<td>Percentage &lt;12kgs</td>
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<td></td>
</tr>
<tr>
<td>P6</td>
<td>ABC+3TC+NFV</td>
<td>100%</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Percentage 12-30kgs (tabs)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P7</td>
<td>ABC+3TC+LPV/r</td>
<td>70%</td>
<td>37</td>
</tr>
<tr>
<td>P8</td>
<td>ABC+3TC+NFV</td>
<td>30%</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>Percentage 12-30kgs (susp)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P9</td>
<td>ABC+3TC+LPV/r</td>
<td>70%</td>
<td>2</td>
</tr>
<tr>
<td>P10</td>
<td>ABC+3TC+NFV</td>
<td>30%</td>
<td>1</td>
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<table>
<thead>
<tr>
<th>Option</th>
<th>PMTCT Prophylaxis (Infants)</th>
<th>Percent</th>
<th>No. Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total No. Patients</td>
<td>100%</td>
<td>46,000</td>
</tr>
<tr>
<td>Q</td>
<td>Infants 5mg Nevirapine (susp)</td>
<td>100%</td>
<td>46,000</td>
</tr>
<tr>
<td>R</td>
<td>Infants on AZT syrup</td>
<td>0%</td>
<td>0</td>
</tr>
</tbody>
</table>
### 1st Line Regimens

<table>
<thead>
<tr>
<th>Phasing In by %</th>
<th>%</th>
<th># Days</th>
<th>Patients</th>
<th>Patient-days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quarter 1</td>
<td>10%</td>
<td>365</td>
<td>118.75</td>
<td>43,344</td>
</tr>
<tr>
<td>Quarter 2</td>
<td>15%</td>
<td>275</td>
<td>178.13</td>
<td>48,984</td>
</tr>
<tr>
<td>Quarter 3</td>
<td>30%</td>
<td>184</td>
<td>356.25</td>
<td>65,550</td>
</tr>
<tr>
<td>Quarter 4</td>
<td>45%</td>
<td>92</td>
<td>534.38</td>
<td>49,163</td>
</tr>
<tr>
<td></td>
<td>100%</td>
<td></td>
<td></td>
<td>1,188</td>
</tr>
</tbody>
</table>

Total patient-days covered: 207,041
Total possible patient-days: 433,438
% total patient-days covered: 47.77%

### 2nd Line Regimens

<table>
<thead>
<tr>
<th>Phasing In by %</th>
<th>%</th>
<th># Days</th>
<th>Patients</th>
<th>Patient-days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quarter 1</td>
<td>5%</td>
<td>365</td>
<td>3</td>
<td>1,141</td>
</tr>
<tr>
<td>Quarter 2</td>
<td>10%</td>
<td>275</td>
<td>6</td>
<td>1,719</td>
</tr>
<tr>
<td>Quarter 3</td>
<td>25%</td>
<td>184</td>
<td>16</td>
<td>2,875</td>
</tr>
<tr>
<td>Quarter 4</td>
<td>60%</td>
<td>92</td>
<td>38</td>
<td>3,450</td>
</tr>
<tr>
<td></td>
<td>100%</td>
<td></td>
<td>63</td>
<td></td>
</tr>
</tbody>
</table>

Total patient-days covered: 9,184
Total possible patient-days: 22,813
% total patient-days covered: 40.26%
### PEDIATRIC REGIMENS YEAR 2006

<table>
<thead>
<tr>
<th>Option</th>
<th>1st Line Regimens (Children)</th>
<th>Percent</th>
<th>No. Patients</th>
<th>New Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total No. Patients</td>
<td></td>
<td>2,093</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Percentage under 3 years, &lt;12kg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P1</td>
<td>AZT+3TC+NVP</td>
<td>50%</td>
<td>732</td>
<td>317</td>
</tr>
<tr>
<td>P2</td>
<td>d4T+3TC+NVP</td>
<td>50%</td>
<td>732</td>
<td>317</td>
</tr>
<tr>
<td></td>
<td>Percentage &gt;3-12 yrs, 12-30kgs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P3</td>
<td>(AZT/3TC+NVP) Aspen co-pack</td>
<td>60%</td>
<td>377</td>
<td>163</td>
</tr>
<tr>
<td>P4</td>
<td>d4T30/3TC/NVP</td>
<td>20%</td>
<td>126</td>
<td>54</td>
</tr>
<tr>
<td>P5</td>
<td>d4T30/3TC+EFV</td>
<td>20%</td>
<td>126</td>
<td>54</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Option</th>
<th>2nd Line Regimens (Children)</th>
<th>Percent</th>
<th>No. Patients</th>
<th>New Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total No. Patients</td>
<td></td>
<td>158</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Percentage &lt;12kgs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P6</td>
<td>ABC+3TC+NFV</td>
<td>100%</td>
<td>16</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Percentage 12-30kgs (tabs)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P7</td>
<td>ABC+3TC+LPV/r</td>
<td>70%</td>
<td>94</td>
<td>57</td>
</tr>
<tr>
<td>P8</td>
<td>ABC+3TC+NFV</td>
<td>30%</td>
<td>40</td>
<td>24</td>
</tr>
<tr>
<td></td>
<td>Percentage 12-30kgs (susp)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P9</td>
<td>ABC+3TC+LPV/r</td>
<td>70%</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>P10</td>
<td>ABC+3TC+NFV</td>
<td>30%</td>
<td>2</td>
<td>1</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Option</th>
<th>PMTCT Prophylaxis (Infants)</th>
<th>Percent</th>
<th>No. Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total No. Patients</td>
<td>100%</td>
<td>56,000</td>
</tr>
<tr>
<td>Q</td>
<td>Infants 5mg Nevirapine (susp)</td>
<td>50%</td>
<td>28,000</td>
</tr>
<tr>
<td>R</td>
<td>Infants on AZT syrup</td>
<td>50%</td>
<td>28,000</td>
</tr>
</tbody>
</table>
### PHASING-IN RATE FOR NEW PATIENTS, BY REGIMEN

<table>
<thead>
<tr>
<th>Phasing-in by Regimen</th>
<th>Existing Patients</th>
<th>New Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Line Regimens</td>
<td>1,188</td>
<td>905</td>
</tr>
<tr>
<td>2nd Line Regimens</td>
<td>63</td>
<td>95</td>
</tr>
</tbody>
</table>

#### 1ST LINE REGIMENS

<table>
<thead>
<tr>
<th>Phasing-in by %</th>
<th>%</th>
<th># Days</th>
<th>Patients</th>
<th>Patient-days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quarter 1</td>
<td>25%</td>
<td>365</td>
<td>226</td>
<td>82,581</td>
</tr>
<tr>
<td>Quarter 2</td>
<td>25%</td>
<td>275</td>
<td>226</td>
<td>62,219</td>
</tr>
<tr>
<td>Quarter 3</td>
<td>25%</td>
<td>184</td>
<td>226</td>
<td>41,630</td>
</tr>
<tr>
<td>Quarter 4</td>
<td>25%</td>
<td>92</td>
<td>226</td>
<td>20,815</td>
</tr>
<tr>
<td></td>
<td>100%</td>
<td></td>
<td>905</td>
<td>207,245</td>
</tr>
</tbody>
</table>

Total patient-days covered: 207,245
Total possible patient-days: 330,325
% total patient-days covered: 62.74%

#### 2ND LINE REGIMENS

<table>
<thead>
<tr>
<th>Phasing-in by %</th>
<th>%</th>
<th># Days</th>
<th>Patients</th>
<th>Patient-days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quarter 1</td>
<td>25%</td>
<td>365</td>
<td>24</td>
<td>8,669</td>
</tr>
<tr>
<td>Quarter 2</td>
<td>25%</td>
<td>275</td>
<td>24</td>
<td>6,531</td>
</tr>
<tr>
<td>Quarter 3</td>
<td>25%</td>
<td>184</td>
<td>24</td>
<td>4,370</td>
</tr>
<tr>
<td>Quarter 4</td>
<td>25%</td>
<td>92</td>
<td>24</td>
<td>2,185</td>
</tr>
<tr>
<td></td>
<td>100%</td>
<td></td>
<td>95</td>
<td>21,755</td>
</tr>
</tbody>
</table>

Total patient-days covered: 21,755
Total possible patient-days: 34,675
% total patient-days covered: 62.74%
# PEDIATRIC REGIMENS YEAR 2007

<table>
<thead>
<tr>
<th>Option</th>
<th>1st Line Regimens (Children)</th>
<th>Percent</th>
<th>No. Patients</th>
<th>New Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total No. Patients</td>
<td></td>
<td>9,000</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Percentage under 3 years, &lt;12kg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P1</td>
<td>AZT+3TC+NVP</td>
<td>50%</td>
<td>3,150</td>
<td>2,833</td>
</tr>
<tr>
<td>P2</td>
<td>d4T+3TC+NVP</td>
<td>50%</td>
<td>3,150</td>
<td>2,833</td>
</tr>
<tr>
<td></td>
<td>Percentage &gt;3-12, 12-30kgs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P3</td>
<td>(AZT/3TC+NVP) Aspen co-pack</td>
<td>60%</td>
<td>1,620</td>
<td>1,457</td>
</tr>
<tr>
<td>P4</td>
<td>d4T30/3TC/NVP</td>
<td>20%</td>
<td>540</td>
<td>486</td>
</tr>
<tr>
<td>P5</td>
<td>d4T30/3TC+EFV</td>
<td>20%</td>
<td>540</td>
<td>486</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Option</th>
<th>2nd Line Regimens (Children)</th>
<th>Percent</th>
<th>No. Patients</th>
<th>New Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total No. Patients</td>
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<td>1,000</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Percentage &lt;12kgs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P6</td>
<td>ABC+3TC+NFV</td>
<td>100%</td>
<td>100</td>
<td>91</td>
</tr>
<tr>
<td></td>
<td>Percentage 12-30kgs tabs</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>P7</td>
<td>ABC+3TC+LPV/r</td>
<td>70%</td>
<td>595</td>
<td>538</td>
</tr>
<tr>
<td>P8</td>
<td>ABC+3TC+NFV</td>
<td>30%</td>
<td>255</td>
<td>231</td>
</tr>
<tr>
<td></td>
<td>Percentage 12-30kgs (susp)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>P9</td>
<td>ABC+3TC+LPV/r</td>
<td>70%</td>
<td>35</td>
<td>32</td>
</tr>
<tr>
<td>P10</td>
<td>ABC+3TC+NFV</td>
<td>30%</td>
<td>15</td>
<td>14</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Option</th>
<th>PMTCT Prophylaxis (Infants)</th>
<th>Percent</th>
<th>No. Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total No. Patients</td>
<td>100%</td>
<td>76,000</td>
</tr>
<tr>
<td>Q</td>
<td>Infants 5mg Nevirapine (susp)</td>
<td>50%</td>
<td>38,000</td>
</tr>
<tr>
<td>R</td>
<td>Infants on AZT syrup</td>
<td>50%</td>
<td>38,000</td>
</tr>
</tbody>
</table>
### PHASING-IN RATE FOR NEW PATIENTS, BY REGIMEN

<table>
<thead>
<tr>
<th>Phasing-in by Regimen</th>
<th>Existing Patients</th>
<th>New Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Line Regimens</td>
<td>2,093</td>
<td>6,908</td>
</tr>
<tr>
<td>2nd Line Regimens</td>
<td>158</td>
<td>843</td>
</tr>
</tbody>
</table>

### 1ST LINE REGIMENS

<table>
<thead>
<tr>
<th>Phasing-in by %</th>
<th>%</th>
<th># days</th>
<th>Patients</th>
<th>Patient-days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quarter 1</td>
<td>25%</td>
<td>365</td>
<td>1,727</td>
<td>630,309</td>
</tr>
<tr>
<td>Quarter 2</td>
<td>25%</td>
<td>275</td>
<td>1,727</td>
<td>474,891</td>
</tr>
<tr>
<td>Quarter 3</td>
<td>25%</td>
<td>184</td>
<td>1,727</td>
<td>317,745</td>
</tr>
<tr>
<td>Quarter 4</td>
<td>25%</td>
<td>92</td>
<td>1,727</td>
<td>158,873</td>
</tr>
<tr>
<td>100%</td>
<td></td>
<td>6,908</td>
<td></td>
<td>1,581,818</td>
</tr>
</tbody>
</table>

Total patient-days covered: 1,581,818

Total possible patient-days: 2,521,238

% total patient-days covered: 62.74%

### 2ND LINE REGIMENS

<table>
<thead>
<tr>
<th>Phasing-in by %</th>
<th>%</th>
<th># days</th>
<th>Patients</th>
<th>Patient-days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quarter 1</td>
<td>25%</td>
<td>365</td>
<td>211</td>
<td>76,878</td>
</tr>
<tr>
<td>Quarter 2</td>
<td>25%</td>
<td>275</td>
<td>211</td>
<td>57,922</td>
</tr>
<tr>
<td>Quarter 3</td>
<td>25%</td>
<td>184</td>
<td>211</td>
<td>38,755</td>
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<tr>
<td>Quarter 4</td>
<td>25%</td>
<td>92</td>
<td>211</td>
<td>19,378</td>
</tr>
<tr>
<td>100%</td>
<td></td>
<td>843</td>
<td></td>
<td>192,933</td>
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</tbody>
</table>

Total patient-days covered: 192,933

Total possible patient-days: 307,513

% total patient-days covered: 62.74%
**ASSUMPTIONS FOR PEDIATRIC QUANTIFICATION**

All < 3 y.o. will take syrups, oral suspensions/solutions.

All 3–12 year olds will take tablets and capsules.

All suspensions in small bottle sizes (e.g. AZT 60ml, NVP 25ml) assumed to be only for PMTCT and not included in ped ART calculation

All NVP syrup for PMTCT is included in quantification of NVP for paediatric ART.

All quantities of tablets and capsules for 4–13 y.o. are based on maximum 30 kg child.

<table>
<thead>
<tr>
<th>Pediatric Dosing Schedule</th>
<th>Drug Formulation</th>
<th>Units/ Patient per Day</th>
<th>Bottles/ patient month PMTCT</th>
<th>Bottles/ Patient per Month</th>
<th>ASSUMPTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 3 y.o.</td>
<td>oral suspensions, syrups</td>
<td></td>
<td></td>
<td></td>
<td>Assume all 3 yo. are 12 kg and body surface .3 m2 -.5 m2</td>
</tr>
<tr>
<td>AZT 240mg/m2/dose bid</td>
<td>AZT 10mg/ml syrup</td>
<td></td>
<td></td>
<td></td>
<td>Body surface of 1 m2 = 30 kg</td>
</tr>
<tr>
<td>GSK</td>
<td>200ml</td>
<td></td>
<td>4</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Combinio pharm</td>
<td>200ml</td>
<td></td>
<td>4</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>GPO</td>
<td>200ml/60ml</td>
<td>13</td>
<td>4</td>
<td>4</td>
<td>if bottle of 60 ml supplied by GPO</td>
</tr>
<tr>
<td>3TC 4 mg/kg/dose bid</td>
<td>3TC 10mg/ml oral suspension</td>
<td></td>
<td></td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>3TC 4 mg/kg/dose bidCipla (50mg/ml :100ml bottle)</td>
<td>100ml</td>
<td></td>
<td>2</td>
<td>Q per month shall vary depending on kg. Below 10 kg one bottle sufficient</td>
<td></td>
</tr>
<tr>
<td>3TC 4mg/kg/dose bid GSK 10mg/ml susp. 240 ml bottle</td>
<td></td>
<td></td>
<td>3</td>
<td>Q per month shall vary depending on kg. Below 10 kg two bottles sufficient</td>
<td></td>
</tr>
<tr>
<td>NVP 200mg/m2/dose od x 14 days.</td>
<td>NVP 10mg/ml oral suspension</td>
<td></td>
<td>3</td>
<td>NVP 2.5 bottles of 240ml per patient rounded up to 3 bottles</td>
<td></td>
</tr>
<tr>
<td>then NVP 200mg/m2/dose bid</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GPO 10mg/ml oral susp</td>
<td>60ml</td>
<td></td>
<td></td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>BI 10mg/ml susp</td>
<td>240ml</td>
<td></td>
<td></td>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>
## ASSUMPTIONS FOR PEDIATRIC QUANTIFICATION

### Pediatric Dosing Schedule

<table>
<thead>
<tr>
<th>Drug Formulation</th>
<th>Units/ Patient per Day</th>
<th>Bottles/ Patient per Month PMTCT</th>
<th>Bottles/ Patient per Month</th>
<th>ASSUMPTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cipla</strong></td>
<td>100ml and 25 ml</td>
<td>24</td>
<td>6</td>
<td>24 bottles/month if 25 ml bottles supplied</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>If one infant dose = 0.6ml NVP, then # doses per bottle = # infants that can be treated</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>If 25ml bottle = 41 infants can receive NVP prophylaxis,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>If 60ml bottle = 100 infants can receive prophylaxis</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>If 100ml bottle = 166 infants. If 240 ml bottle = 400 infant doses</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Question is, how many mothers (assuming 1 infant per mother) will actually receive NVP for PMTCT in year 2005, year 2006? Then figure out number of bottles needed. Short shelf life (expiry dates) need to be taken into account for huge wastage, esp the 240 ml bottles.</td>
</tr>
<tr>
<td><strong>d4T 1mg/kg/dose bid</strong></td>
<td><strong>d4T 1mg/ml PFR 200mg per bottle</strong></td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Needed 2.5, rounded to 3 bottles</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>comes in powder of 1mg/ml</td>
</tr>
<tr>
<td><strong>GPO 1 mg/ml/bottle 60 ml</strong></td>
<td>12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>GPO 5 mg/ml/bottle 60 ml</strong></td>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>BMS 200ml bottle</strong></td>
<td>5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ABC 8mg/kg/dose bid</strong></td>
<td><strong>ABC 20mg/ml oral solution GSK</strong></td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ddl 90mg/m2/dose bid</strong></td>
<td><strong>ddl 10mg/ml PFR 2g (&lt; 1 yo.)</strong></td>
<td>1</td>
<td></td>
<td>Only &lt; 1 yo. take ddl 10mg/ml oral solution (1 bottle = - 2,000mg)</td>
</tr>
<tr>
<td></td>
<td><strong>BMS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### ASSUMPTIONS FOR PEDIATRIC QUANTIFICATION (CONTINUED)

<table>
<thead>
<tr>
<th>Pediatric Dosing Schedule</th>
<th>Drug Formulation</th>
<th>Units/patient per Day</th>
<th>Bottles/patient month PMTCT</th>
<th>Bottles/Patient per Month</th>
<th>ASSUMPTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>NFV 75mg/kg/dose bid &lt; 1 y.o.</td>
<td>NFV 250mg tab crushed</td>
<td>5</td>
<td>8</td>
<td>8 bottles needed if child 12 kg</td>
<td>NFV 250mg tabs to be used for all &lt; 3 y.o. and 3 - 13 y.o.</td>
</tr>
<tr>
<td>Roche, Switzerland, powder for susp. 50mg/g; 144g</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LPV/r (1.2mg/kgLPV + 3mg/kg RTV bid)</td>
<td>LPV/r 80mg/20mg/ml syrup</td>
<td></td>
<td>1</td>
<td>1</td>
<td>LPV/r only for children &gt; 6 months</td>
</tr>
<tr>
<td>Abbot laboratones, 20mg/80mg/ml : 60 ml bottle</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 bottle is the equivalent of a pack of 5 x 60ml bottles</td>
</tr>
<tr>
<td>4 – 13 yo</td>
<td>capsules, tablets</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AZT 240mg/m2/dose bid</td>
<td>AZT 100mg capsule 12kg - 30kg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>AZT300mg/3TC 150mg 1/2 tablet bid &lt; 30kg</td>
<td>1</td>
<td>80% pts &lt;30kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>AZT300mg/3TC 150mg 1 tablet bid &gt; 30kg</td>
<td>2</td>
<td>20% pts &gt;30kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3TC 4 mg/kg/dose bid</td>
<td>3TC 150mg tablet</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NVP 200mg/m2/dose od x 14 days.</td>
<td>NVP 200mg tablet</td>
<td></td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d4T/3TC/NVP</td>
<td>30mg/150mg/200mg, 1/2 tab bid</td>
<td>1</td>
<td></td>
<td>Assume kids will get half adult dose twice a day</td>
<td></td>
</tr>
<tr>
<td>d4T/3TC fixed dose</td>
<td>d4T/3TC 30mg/150mg 1/2 tab bid</td>
<td>1</td>
<td></td>
<td>Assume kids will get half adult dose twice a day</td>
<td></td>
</tr>
</tbody>
</table>
## ASSUMPTIONS FOR PEDIATRIC QUANTIFICATION (CONTINUED)

<table>
<thead>
<tr>
<th>Pediatric Dosing Schedule</th>
<th>Drug Formulation</th>
<th>Units/ Patient per Day</th>
<th>Bottles/ Patient per Month PMTCT</th>
<th>Bottles/ Patient per Month</th>
<th>ASSUMPTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>EFV 50mg caps</td>
<td>EFV 50mg, 20-29kg, 3caps OD</td>
<td>3</td>
<td></td>
<td></td>
<td>Based on MSF dosing schedule, between 15-29kgs, its 1, 2 and 3 50mg caps OD, we took the highest dose in the weight band</td>
</tr>
<tr>
<td>ABC 8mg/kg/dose bid</td>
<td>ABC 300mg tablet</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ddI 90mg/m2/dose bid</td>
<td>ddI 25mg, 50mg, 100mg tablet bid</td>
<td>2</td>
<td></td>
<td></td>
<td>ddl 25mg, 50mg, 100mg tablets for 1 - 13 y.o.</td>
</tr>
<tr>
<td>NFV 60mg/kg/dose bid (1 - 13 y.o.)</td>
<td>NFV 250mg tab crushed</td>
<td>14</td>
<td></td>
<td></td>
<td>NFV 250mg tabs to be used for all &lt; 3.y.o. and 3 - 13 y.o.</td>
</tr>
<tr>
<td>LPV/r (12mg/kgLPV+3mg/kg RTV bid)</td>
<td>LPV/r 133.3mg/33.3mg capsule</td>
<td>4</td>
<td></td>
<td></td>
<td>12 kg = LPV/r 133.3mg/33.3 mg one capsule od 20kg - 40kg = LPV/r 133.3mg/33.3mg two capsules bid &gt; 40kg = LPV/r 133.3mg/33.3mg 3 capsules bid</td>
</tr>
</tbody>
</table>
QUANTITY REQUIRED (CHILDREN)  FORECAST YEARS 2005–2007

Assume USG funds will be used to purchase pediatric formulations, so use originator bottle/patient/month number whenever possible.

We did not take into account two options that were used for adults: a) dosing was calculated for the highest weight within a weight band, assuming some would be wasted; and b) no half dose for the 15 day step-up period for Nevirapine was calculated, instead the full dose for the full period was used.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Total Patients</td>
<td>Patients per Patient-day</td>
<td>Units per Patient-month</td>
<td>Bottles per Year</td>
<td>Bottles per Patient-month</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total Patients</td>
<td>Patients per Patient-day</td>
<td>Units per Patient-month</td>
<td>Bottles per Year</td>
<td>Bottles per Patient-month</td>
</tr>
<tr>
<td>P1</td>
<td>Under 3 yrs.&lt;12kg</td>
<td>AZT syrup 10mg/ml</td>
<td>416</td>
<td>72,464</td>
<td>2,415</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3TC syrup 10mg/ml</td>
<td>3</td>
<td>7,246</td>
<td>3</td>
<td>22,424</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NVP syrup 10mg/ml</td>
<td>3</td>
<td>7,246</td>
<td>3</td>
<td>22,424</td>
</tr>
<tr>
<td>P2</td>
<td>Under 3 yrs.&lt;12kg</td>
<td>d4T syrup 1mg/ml powder for syrup</td>
<td>416</td>
<td>72,464</td>
<td>2,415</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3TC syrup 10mg/ml</td>
<td>3</td>
<td>7,246</td>
<td>3</td>
<td>22,424</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NVP syrup 10mg/ml</td>
<td>3</td>
<td>7,246</td>
<td>3</td>
<td>22,424</td>
</tr>
<tr>
<td>P3</td>
<td>Over 3-12yrs. 12-30kg</td>
<td>(AZT/3TC + NVP) Aspen co-pack</td>
<td>214</td>
<td>37,267</td>
<td>1</td>
<td>37,267</td>
</tr>
<tr>
<td>P4</td>
<td>Over 3-12yrs. 12-30kg</td>
<td>d4T/3TC/NVP (30mg)</td>
<td>71</td>
<td>12,422</td>
<td>1</td>
<td>12,422</td>
</tr>
<tr>
<td>P5</td>
<td>Over 3-12yrs. 12-30kg</td>
<td>d4T/3TC (30mg)</td>
<td>71</td>
<td>12,422</td>
<td>1</td>
<td>12,422</td>
</tr>
<tr>
<td></td>
<td>Under 3 yrs.&lt;12kg</td>
<td>EFV 50mg cap</td>
<td>3</td>
<td>37,267</td>
<td>3</td>
<td>115,323</td>
</tr>
</tbody>
</table>

2nd Line Regimens
## QUANTITY REQUIRED (CHILDREN) FOR FORECAST YEARS 2005–2007 (CONTINUED)

<p>| Option | 1st Line Regimens | Total Patients | Patients per month | Units per Patient per day | Bottles per Patient per month | Total Units per 100 Patients | Bottles per Patient per Year | Total Patients | Patients per month | Units per Patient per day | Bottles per Patient per month | Total Units per 100 Patients | Bottles per Patient per Year | Total Patients | Patients per month | Units per Patient per day | Bottles per Patient per month | Total Units per 100 Patients | Bottles per Patient per Year |
|--------|------------------|----------------|------------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|
| P6     | ABC+3TC+NFV      | 6              | 9.18             | 31             | 2              | 61             | 16             | 4,457          | 149             | 2              | 297            | 100            | 26,473         | 882            | 2              | 1,765          |
|        | ABC 20mg/ml oral | 6              | 9.18             | 31             | 2              | 61             | 16             | 4,457          | 149             | 2              | 297            | 100            | 26,473         | 882            | 2              | 1,765          |
|        | solution         |                |                  |                |                |                |                |                |                 |                |                |                |                |                |                |                |                |                |                |                |
|        | 3TC 10mg/ml susp | 6              | 9.18             | 31             | 2              | 61             | 16             | 4,457          | 149             | 2              | 297            | 100            | 26,473         | 882            | 2              | 1,765          |
|        | 240ml bottle     |                |                  |                |                |                |                |                |                 |                |                |                |                |                |                |                |                |                |                |                |
|        | NFV 50mg/g powder| 6              | 9.18             | 8              | 4              | 245            | 16             | 4,457          | 8               | 1,188          | 100            | 26,473         | 882            | 8              | 7,060          |
|        | for susp 144g    |                |                  |                |                |                |                |                |                 |                |                |                |                |                |                |                |                |                |                |                |
| P7     | ABC+3TC+LPV/r    | 37             | 5,465            | 2              | 10,929         | 94             | 26,518         | 2              | 53,035         | 2              | 53,035         | 2              | 157,516        | 2              | 315,032        |
|        | ABC 300mg tablet  |                |                  |                |                |                |                |                |                 |                |                |                |                |                |                |                |                |                |                |                |
|        | 3TC 150 mg tablet | 37             | 5,465            | 2              | 10,929         | 94             | 26,518         | 2              | 53,035         | 2              | 53,035         | 2              | 157,516        | 2              | 315,032        |
|        | LPV/r 133.3/33.3 caps | 37          | 5,465            | 14             | 76,506         | 94             | 26,518         | 14             | 371,247        | 14             | 371,247        | 14             | 307,222        | 2              | 220,522        |
| P8     | ABC+3TC+NFV      | 16             | 2,342            | 2              | 4,684          | 40             | 11,365         | 2              | 22,729         | 2              | 22,729         | 2              | 67,507         | 2              | 135,014        |
|        | ABC 300mg tablet  |                |                  |                |                |                |                |                |                 |                |                |                |                |                |                |                |                |                |                |                |
|        | 3TC 150 mg tablet | 16             | 2,342            | 2              | 4,684          | 40             | 11,365         | 2              | 22,729         | 2              | 22,729         | 2              | 67,507         | 2              | 135,014        |
|        | NFV 250mg tab     | 16             | 2,342            | 4              | 9,368          | 40             | 11,365         | 4              | 45,459         | 4              | 45,459         | 4              | 67,507         | 4              | 270,027        |
| P9     | ABC+3TC+NFV      | 1              | 138              | 5              | 2              | -              | 2              | 1,104          | 37             | 2              | -              | 74             | 15             | 8,116         | 271            | 2              | 541            |
|        | ABC 20mg/ml oral | 1              | 138              | 5              | 2              | -              | 2              | 1,104          | 37             | 2              | -              | 74             | 15             | 8,116         | 271            | 2              | 541            |
|        | sup               |                |                  |                |                |                |                |                |                 |                |                |                |                |                |                |                |                |                |                |                |
|        | 3TC 10mg/ml susp  | 1              | 138              | 5              | 3              | 14             | 2              | 1,104          | 37             | 3              | 110            | 15             | 8,116         | 271            | 3              | 812            |
|        | 240ml bottle      |                |                  |                |                |                |                |                |                 |                |                |                |                |                |                |                |                |                |                |                |
|        | NFV 50mg/g powder | 1              | 138              | 5              | 8              | 37             | 2              | 1,104          | 37             | 8              | 294            | 15             | 8,116         | 271            | 8              | 2,164          |                |                |                |                |
|--------|------------------|-----------|---|-----------|---|-----------|
|        |                  | Units     | Bottles | Total Units | Bottles | Total Units |
|        |                  | per Patient-day | per Year | /tabs/caps | per Year | /tabs/caps |
| P10    | ABC+3TC+LPV/r     | 2 321    | 2 21 | 6 1,125  | 2 75 | 35 5,121  |
|        | ABC 20mg/ml oral solution | 2 321 | 11 | 6 1,125 | 2 75 | 35 5,121 |
|        | 3TC 10mg/ml susp 240ml bottle | 2 321 | 11 | 6 1,125 | 2 75 | 35 5,121 |
|        | LPV/r 80mg/20mg/ml | 2 321 | 11 | 6 1,125 | 2 75 | 35 5,121 |
|        | PMTCT Prophylaxis (infants) | - | - | - | - | - |
| Q      | NVP 10mg/ml oral susp 240ml bottle | 46,000 | 144 | 28,000 | 0.5 | 38,000 |
| R      | AZT syrup 10mg/ml 200ml bottle | 28,000 | 1 | 28,000 | 0.5 | 38,000 |</p>
<table>
<thead>
<tr>
<th>DRUG PRODUCT</th>
<th>Basic Unit</th>
<th>Total No. Basic Units Required 2005</th>
<th>Total No. Basic Units Required 2006</th>
<th>Total No. Basic Units Required 2007</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1st LINE REGIMEN DRUGS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d4T (30mg)/3TC/NVP</td>
<td>tablet</td>
<td>2,224,098</td>
<td>6,632,752</td>
<td>13,415,371</td>
</tr>
<tr>
<td>TOTAL ADULT + PEDIATRIC</td>
<td></td>
<td>2,236,521</td>
<td>6,671,193</td>
<td>13,572,422</td>
</tr>
<tr>
<td>d4T(30)/3TC</td>
<td>tablet</td>
<td>614,038</td>
<td>1,382,041</td>
<td>2,742,039</td>
</tr>
<tr>
<td>TOTAL ADULT + PEDIATRIC</td>
<td></td>
<td>626,461</td>
<td>1,420,482</td>
<td>2,899,090</td>
</tr>
<tr>
<td>d4T(40)/3TC/NVP</td>
<td>tablet</td>
<td>1,779,279</td>
<td>5,779,634</td>
<td>13,461,930</td>
</tr>
<tr>
<td>d4T(40)/3TC</td>
<td>tablet</td>
<td>580,195</td>
<td>1,380,103</td>
<td>2,802,121</td>
</tr>
<tr>
<td>(AZT/3TC + NVP) Aspen co-pack</td>
<td>tablet</td>
<td>4,003,377</td>
<td>9,498,956</td>
<td>16,243,535</td>
</tr>
<tr>
<td>TOTAL ADULT + PEDIATRIC</td>
<td></td>
<td>4,040,645</td>
<td>9,614,279</td>
<td>16,714,688</td>
</tr>
<tr>
<td>EFV 600mg</td>
<td>capsule</td>
<td>578,266</td>
<td>1,582,486</td>
<td>3,114,283</td>
</tr>
<tr>
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*(CONTINUED)*
DELIVER
DELIVER, a six-year worldwide technical assistance support contract, is funded by the President’s Emergency Plan for AIDS Relief (PEPFAR) through the U.S. Agency for International Development (USAID).

Implemented by John Snow, Inc. (JSI), (contract no. HRN-C-00-00-00010-00) and subcontractors (Manoff Group, Program for Appropriate Technology in Health [PATH], and Social Sectors Development Strategies, Inc.), DELIVER strengthens the supply chains of health and family planning programs in developing countries to ensure the availability of critical health products for customers. DELIVER also provides technical management of USAID’s central contraceptive management information system.

Recommended Citation

Abstract
The successful provision of any HIV counseling and testing services—including VCT and PMTCT—depends on the continuous availability of HIV tests, as well as on the supply of a range of other HIV/AIDS-related commodities. Without adequate supplies of HIV tests and consumable supplies, or an effective supply chain to deliver the commodities to facilities on a continuous basis, investments in provision of ART and other services will not be maximized. The specific characteristics of HIV tests and of how they are used within counseling and testing programs pose particular challenges for managing the supply chain. Although some general considerations for managing the supply chain for HIV tests are discussed in this guide, the primary focus and purpose of the guide are to describe the process and methodologies used for quantifying HIV test needs. Quantification of health commodities is a process which includes estimating the quantities and the cost of products required to meet customer demand, and to fill the pipeline with adequate stock levels taking into account service delivery capacity, supply pipeline requirements, and resources available for procurement.
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ACRONYMS

AIDS acquired immunodeficiency syndrome
AMAD average monthly adjusted demand
AMQR average monthly quantity required
ANC antenatal care
ART antiretroviral therapy
ARV antiretroviral drugs
CDC Centers for Disease Control and Prevention
DHS Demographic and Health Survey
ELISA enzyme-linked immunosorbent assay
HIV human immunodeficiency virus
LMIS logistics management information system
MOH Ministry of Health
MTCT mother-to-child transmission
NAC National AIDS Committee
NACP National AIDS Control Program
NGO nongovernmental organization
OI opportunistic infection
PCR polymerase chain reaction
PEP post-exposure prophylaxis
PEPFAR President’s Emergency Plan for AIDS Relief
PMTCT prevention of mother-to-child transmission
RTD rapid test devices
STG standard treatment guidelines
STI sexually transmitted infection
TB tuberculosis
UNAIDS United Nations Programme on HIV/AIDS
UNICEF United Nations Children’s Fund
VCT voluntary counseling and testing
WHO World Health Organization
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/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/AIDS services. The publication is also dedicated to friends and counterparts who have worked with DELIVER, 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/AIDS and laboratory commodities, we recognize that comprehensive HIV/AIDS and laboratory programs require the supply chain to manage and deliver a broad range of several hundred public health commodities.

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PREFACE

A major challenge to initiation and expansion of HIV counseling and testing services in resource-poor countries that have been most affected by the HIV/AIDS epidemic has been the limited capacity of health commodity supply chains to ensure a reliable supply of the products at service delivery sites to support HIV prevention, care, and treatment programs. Successful provision of any HIV counseling and testing services—including voluntary counseling and testing (VCT) and testing for prevention of mother-to-child transmission (PMTCT)—depends on the continuous availability of HIV tests, as well as on the supply of a range of other HIV/AIDS-related commodities.

These commodities include items provided in conjunction with HIV testing and counseling services such as condoms; contraceptives; other laboratory reagents and supplies; drugs for the treatment of sexually transmitted infections (STIs), tuberculosis (TB), and other opportunistic infections (OIs); protective gear for infection prevention and health worker safety; and a host of consumable medical supplies. A significant number of public sector programs in resource-poor countries urgently need enhanced capacity in quantification, financing, procurement, and delivery of HIV/AIDS-related commodities that are essential in most supply chain management functions. Global efforts to coordinate quantification, financing, and procurement are also critical and must complement country-based initiatives.

HIV counseling and testing—particularly VCT—are often considered the gateway to prevention and care (Joint United Nations Programme on HIV/AIDS 2002). Individuals must learn their status before they can receive other HIV/AIDS care and treatment services, especially antiretroviral therapy (ART). Without adequate supplies of HIV tests and consumable supplies, or without an effective supply chain to deliver the commodities to facilities on a continuous basis, investments in the provision of ART and in other HIV/AIDS services will not be maximized.

The specific characteristics of HIV tests and of how they are used within counseling and testing programs pose particular challenges for managing the supply chain. Although some general considerations for managing the supply chain for HIV tests are discussed in this guide, the primary focus and purpose of the guide are to describe the process and methodologies used for quantifying HIV test needs. Furthermore, this guide does not cover the quantification of the consumables required for some HIV test kits. Often, those items are very specific to the type and to the brand of kit chosen. Increasingly, many of the newer HIV rapid test kits are self-contained and do not require additional supplies.

This guide can be used as a standalone document and can also be complemented by a number of other useful references. It was written as a companion piece to the ProQ Software. Another companion piece, *Guide for Quantifying Laboratory Supplies* (DELIVER 2006), covers the quantification of consumable supplies used in laboratories. Further technical aspects of managing the supply chain for HIV tests are discussed in depth in other sections of *Guidelines for Managing the HIV/AIDS Supply Chain* (DELIVER 2005).

This guide for quantifying HIV tests draws from the collective experience of DELIVER logistics advisors who have been involved in a range of activities to improve management of the supply chains for HIV/AIDS commodities in several countries that are hardest hit by the epidemic. The list of countries includes Ghana, Kenya, Malawi, Mozambique, Nepal, Nigeria, South Africa, Tanzania, Uganda, Ukraine, Zambia, and
Zimbabwe. DELIVER’s experience indicates that two of the most critical supply chain interventions for HIV testing and counseling programs at this time are the need to:

- Establish robust data collection and reporting systems to improve the availability and quality of data on HIV testing services and commodities
- Build capacity in quantification of HIV test requirements at the country and program levels to enhance informed decision making regarding financing and procurement of commodities, thus maximizing opportunities for continuous product availability in a country.

The DELIVER experience and lessons learned in quantification of HIV tests have been incorporated into the step-by-step approach to quantification presented in this guide. It is important to recognize that each country, each program, and each quantification will be unique as programs mature, as technologies and clinical practice evolve, as new HIV tests become available, and as logistics management information systems (LMIS) improve to enable more evidence-based quantifications. This guide is, therefore, a work in progress that will be reviewed and updated over time to reflect the growing body of knowledge and best practices in HIV counseling and testing and in management of HIV test supply chains.
INTRODUCTION TO QUANTIFICATION

Quantification of health commodities is a process that includes estimating the quantities and the cost of products as required to meet customer demand and to fill the pipeline with adequate stock levels. The process takes into account service delivery capacity, supply pipeline requirements, and resources available for procurement. Quantification consists of four distinct steps: forecasting demand, estimating requirements, calculating the costs for procuring the requirements, and, if needed, adjusting the final quantities to procure according to the amount of funding available.

The results of quantification may be used (a) to calculate specific order quantities and to plan shipment schedules for short-term procurement planning, and (b) to assist in medium- to long-term program planning and resource mobilization efforts.

DEFINITION OF TERMS

Given the level of precision required to conduct accurate quantifications, it is important to clarify the use of specific terms within the context of this document that may be used and understood differently in other contexts.

CUSTOMER

Within the context of quantification of health commodities, the customer is the end user who is understood to be the patient, the client, or the provider who will ultimately receive, use, or consume the product within the forecast period.

CUSTOMER DEMAND

Therefore, customer demand refers to the specific quantities of the product to be dispensed or used to be able to meet customers’ requests or their actual rather than their potential demand for health services within the forecast period.

PRODUCT WASTAGE

*Product wastage* is the estimated quantity of product that is expected to be wasted through normal usage or through nonuse. Wastage through normal use or nonuse can occur, for example, through spillage, through incorrect measurement or damage during use, or by accounting for quantities of a product that may be returned by patients and that cannot be re-used or dispensed to other patients. Product wastage is based on an accepted standard percentage of total product consumption.
**STEPS IN QUANTIFICATION**

Figure 1 represents the steps in the quantification process.

**Figure 1. The Quantification Process**

**FORECASTING DEMAND**

*Forecasting demand* means estimating the quantity of products (e.g., drugs to be dispensed, HIV tests or laboratory reagents to be used) to meet customer demand for a future period of time. For health commodities, the number of customers to be served and the cases to be treated, along with the forecasted demand, may need to be adjusted to reflect (a) the scope of the quantification, which may be a national-level quantification or may be for a specific program, service sector, geographic region, level of service, or patient target group; (b) the purpose of use within the quantification (for example, drugs for both antiretroviral therapy [ART] and prevention of mother-to-child transmission [PMTCT] services), or HIV tests for only voluntary control and testing (VCT) and PMTCT services; and (c) the program's service capacity according to the volume of services that can be provided, given the existing infrastructure, staff availability and staff skills, and customer access to services.

In the case of HIV tests and laboratory reagents and supplies, the forecast may need to include additional quantities for quality control and training, in addition to client testing. For products that have multiple uses, it may be necessary to forecast demand separately for each use. Examples of forecasting demand separately could include forecasting demand for an antibiotic prescribed for treating sexually transmitted infections (STIs) and opportunistic infection (OIs) under different treatment guidelines, or forecasting usage of an HIV test for diagnostic or confirmatory testing under different testing protocols for PMTCT, HIV counseling and testing (HCT), or VCT.
ESTIMATING REQUIREMENTS

Estimating requirements consists of determining the quantity of each product needed to meet the forecasted demand and ensuring that the pipeline has adequate stock levels to maintain continuous supply to service delivery points. The requirements estimate for the forecast period is determined by calculating additional quantities of product needed to cover any expected product wastage, quality control, lead times, and buffer stocks to the forecasted demand. The requirements estimate is then adjusted by subtracting the quantity of each product already in the system (stock on hand) and any quantities already ordered but not yet received (quantity on order).

In some cases, the forecasted demand, and consequently the requirements estimate, may need to be reduced to accommodate constraints in the storage and distribution capacity of the logistics system.

ESTIMATING COSTS

Estimating costs involves calculating the cost of procuring all the product requirements. In addition to the commodity cost, other procurement, shipping, handling, customs clearance, storage, and distribution costs may also be included in the total cost estimate.

DETERMINING QUANTITY TO PROCURE

Determining the quantity to procure consists of identifying the quantities of products to be procured. If the cost estimate does not exceed the total funds available, then this step is straightforward and requires little to no adjustment of the estimated requirements. In most cases, the quantity to procure will equal the requirements estimate. If, however, the cost estimate is greater than the available funding envelope, an adjustment must be made to the estimated requirements, either by reducing the number of items to be procured or by recalculating the quantities required of each individual product.

For most public health programs, this step involves prioritizing the items to be purchased according to the conditions to be treated or the people to be served, and then reducing the quantity to procure to fit available funds. In such cases, a variety of methods can be used to arrive at the final quantity of product to be procured, including the use of epidemiological profiles, or ABC and vital, essential, nonessential (VEN) analyses. For HIV/AIDS programs, this step may result in a reduction of the number of people who can be tested for HIV infection or the number of patients who can initiate ART within the period of the forecast.

FORECASTING METHODOLOGIES

In general, the methodology that is selected for forecasting future demand for services and commodity needs is based on the availability and quality of data on (a) the rate of consumption of drugs or commodities used and (b) the number and type of patients receiving services, as well as on program policies and expansion plans. The following types of data may be used to guide the forecast:

- Demographic data based on characteristics of the target population (e.g., age, sex, geographic location, and urban or rural location)
- Morbidity data on prevalence or incidence of disease or infection in the target population
- Service statistics data on the number of service delivery sites, the volume of services or number of patients per site, and the type of service received
- Logistics data on consumption or use, losses, and adjustments to inventory, and the stock on hand at the various levels of the in-country supply chain
For new and expanding programs or services and for existing programs for which those types of data may be unavailable, unreliable, or not predictive of future demand, forecasts may be based on program targets, such as the number of patients expected to access and receive treatment within the period of the forecast. Targets for expanding programs should be based on realistic service delivery and supply chain capacity, as well as on available resources. Although forecasts based on program targets are commonly used to determine commodity needs and cost estimates for procurement, program targets may also be based on the number of patients who could be treated, given a specific amount of funding available and the commodity cost per patient.

Forecasts based on demographic, morbidity, or target data alone will most often overestimate commodity requirements because they do not take into account the actual volume of services being provided or that can be provided, or the quantities of commodities being dispensed or used. Wherever possible, service statistics data on the actual number of patients being treated, as well as logistics data on the actual quantities of drugs dispensed to patients or the actual quantities of commodities used, should be incorporated into the forecast.

THE CONSUMPTION-BASED METHODOLOGY

The consumption-based methodology uses logistics data on consumption of commodities in the past as a basis for projecting future needs. Estimates of increases in consumption or other changes in consumption for each product during the period of the forecast are based on past trends in consumption or product usage. Use of the consumption-based methodology requires the availability of data on the quantities of drugs actually dispensed to patients or on the commodities used at service delivery points over a specified period. In many cases, timely and accurate consumption data are not available, and, even if they are available, consumption data alone will not be indicative of future demand in new programs and in expanding programs. Assumptions will need to be made about the rate of program growth, about prescribing and dispensing practices, and about patient needs to complete the quantification.

THE ADJUSTED CONSUMPTION METHODOLOGY

The adjusted consumption methodology is an adaptation of the consumption-based methodology that uses the consumption data from one or more facilities with reliable data and extrapolates from that data to estimate the quantities of commodities needed at other, similar facilities for which no data or unreliable data exist. Again, this methodology requires the availability of timely and accurate consumption data on quantities of drugs dispensed to patients or quantities of commodities used at one or more service delivery sites.

THE MORBIDITY-BASED METHODOLOGY

In the morbidity-based methodology, the estimation of commodity needs is based on the application of standard treatment guidelines, testing algorithms, or other treatment protocols to the projected number of patients expected to receive treatment or services within the forecast period. The projected number of patients to be forecasted may be based on demographic data, morbidity data, service statistics data, program targets, or a combination of those data.

Using morbidity-based methodology for estimating commodity requirements requires that data on the actual number of patients treated or services provided and the estimated number of new patients to be diagnosed and treated or services to be provided within the period of the forecast must be available or must be arrived at through informed assumptions. Standard treatment guidelines, testing protocols, or other policy guidelines should be clearly documented, disseminated, and assumed to be adhered to by all service providers who have been adequately trained. The accuracy of morbidity-based forecasts depends on the degree to which STGs are followed and on the availability of prescribed drugs or commodities when they are needed.
In practice, forecasts may be conducted using two or more types of data and a combination of methodologies. For example, the results of a consumption-based forecast and a morbidity-based forecast may be compared and adjusted to arrive at a best estimate of future commodity requirements.

**THE IMPORTANCE OF STANDARDIZATION IN QUANTIFICATION**

A critical prerequisite for conducting quantification for any health commodity is the existence of clear, well-defined STGs or testing protocols for defining the specific use of individual commodities for treatment or testing. In the case of HIV testing programs, given the fact that there are multiple purposes for using HIV tests for testing, as well as different implications for positive or negative results, it is critical that standardization of testing protocols occurs and that standardization precedes quantification. The importance of standardized testing protocols is magnified in the case of new, rapidly expanding HIV/AIDS programs for the following reasons:

- Each purpose of use (e.g., VCT, PMTCT, Blood Safety) may require a different protocol that is based on HIV prevalence, purpose of the testing, and number of different tests available in the program. For example, for unlinked blood safety testing, ensuring the safety of the blood supply is the highest priority, so all positive tests are automatically discarded without retesting. Such a procedure will require a different protocol from that used for VCT, in which case, it may be important to confirm that the first positive test result is truly a positive result or whether a second test or a third test might be required.

- The testing protocols are a guide for the individuals administering the tests. Given that programs are in the process of expanding and that the number of skilled and experienced service providers who perform HIV testing is small relative to the number of testing sites, the protocols are an essential tool for helping new providers provide quality test results to clients.

- HIV test technology is evolving rapidly, with new tests being developed and an array of test brands already available on the international market. Not all tests, however, perform equally in producing highly sensitive or specific results. For diagnostic testing, usually a combination of tests are used to maximize the service provider’s ability to provide the most accurate test result, in the shortest amount of time, at the most optimal cost. Without standard protocols in place, providers may choose expensive and ineffective tests, which might result in clients receiving incorrect test results and in compromising the credibility of the entire program.

Standardization of testing protocols is especially critical in the context of quantification. In the absence of quality logistics data, quantification will likely be conducted using the morbidity-based methodology. To enhance the accuracy of the quantification using this method, standard testing protocols must exist and must be clearly documented and disseminated. Because of the fact that tests are often conducted in combination, quantification is extremely challenging without the existence of standard protocols and can result in significant quantities of wasted tests. DELIVER’s experience has been that the lack of standardization of testing protocols can significantly delay the quantification and procurement processes, thus compromising product availability to programs.
Before one quantifies HIV test requirements, it is important to have a basic knowledge of the characteristics of HIV tests and the ways in which they are used for HIV testing.

**TYPES OF HIV TESTS**
There are as many as 100 or more brands of HIV tests, and the technology is evolving rapidly. In the next few years, many new tests will likely replace current ones. Table 1 shows the three basic groups that the majority of HIV tests being used in developing country settings fall into. Refer to the *HIV Tests Fact Sheets* (DELIVER 2006) for detailed information including estimated costs.

**TABLE 1. HIV TESTS**

<table>
<thead>
<tr>
<th>Test</th>
<th>Sites of Use</th>
<th>Advantages</th>
<th>Limitations</th>
</tr>
</thead>
</table>
| Simple/rapid assay (Rapid test device, or RTD) | Small labs, VCT sites, PMTCT sites, STI, and TB clinics, emergency care centers | • Easy to use and interpret test results  
• Results within 10–30 minutes  
• No minimum volume of tests required  
• Requires minimal equipment  
• Does not require highly skilled staff members  
• Has many newer tests that can be stored at room temperature  
• When used in combination, results that are as reliable as ELISAs  
• Can be used on various types of specimens, including whole blood  
• Oral fluid tests that have been developed recently, that are noninvasive, and that do not require sharps  
• Can be used to do on-site or point-of-care testing | • Small-scale testing  
• Considerable variation in sensitivity; however, this variation often depends on the type of specimen (i.e., whole blood, serum, oral fluid)  
• Cold chain sometimes required  
• May cost more per individual test  
• Some products that are less sensitive for sero-convertors  
• Use of rapid tests at multiple sites in resource-poor countries that will pose quality assurance challenges |
### Sites of Use

- **enzyme linked immunosorbent assays (ELISA)**
  - Large hospitals, blood banks, or reference laboratories
  - Advantages:
    - Highly sensitive, especially for picking up sero-convertors
    - Batch testing
    - Can be automated
    - Easier to conduct quality assurance testing, because tests are performed in fewer, high-volume laboratories
  - Limitations:
    - Requires more time to obtain results (1–3 hours) and even longer if not at point of care
    - Need sophisticated equipment and equipment maintenance
    - Cold chain always required
    - Need minimum volume of tests for maximum efficiency
    - Requires skilled technicians

- **Western blot**
  - Large teaching hospitals, reference laboratories, and the National Reference Laboratory
  - Advantages:
    - The “Gold Standard”
    - Detects all antibodies present
  - Limitations:
    - Requires skilled and experienced personnel
    - Nonroutine test (small batches only, usually <10 in a batch used for research and for clarifying indeterminate results)

### PRIMARY USES OF HIV TESTS

Understanding the purpose of use for the HIV tests that are being quantified is a critical step in defining the scope of the quantification. The following list represents the most common uses of HIV tests in resource-limited settings.

### ENSURING BLOOD SAFETY

Testing blood and blood products for HIV and other infectious diseases is a relatively simple intervention that prevents disease transmission through transfusion. Testing for HIV and for other infectious diseases allows for infected or suspect blood to be discarded or destroyed, thereby ensuring the safety of the blood supply.

The World Health Organization’s (WHO’s) Global Database on Blood Safety, however, indicates that 80 percent of the world’s population does not have access to safe and reliable blood (WHO 2001a). High rates of HIV and hepatitis infection among donors in some countries make blood transfusions a serious risk. WHO reports that unsafe blood products cause 5–10 percent of new HIV infections. In some blood safety programs, blood donors are informed of their sero-status (linked testing). In other programs, blood donors are not informed of the results of testing (unlinked testing). HIV testing for blood safety varies in its location as well. Sometimes blood safety testing occurs at the community level, using outreach services, and at other times, blood safety testing is consolidated at regional or central-level blood transfusion centers.

### VOLUNTARY COUNSELING AND TESTING

Voluntary HIV counseling and testing (VCT) has been the primary diagnostic testing strategy to date in expanding programs. VCT is often considered a pivotal strategy for HIV/AIDS prevention, care, support, and treatment activities. Individuals who test negative can take appropriate measures to avoid becoming infected. Individuals who test positive can access treatment, care, and support services, including condom distribution,
PMTCT, prevention, and clinical management of HIV-related illnesses, STI and TB control, psychosocial and legal support, and antiretroviral therapy, if available.

In VCT, the speed of the test is critical, because it is important to give the client the test result during the visit. In most settings, some percentage of clients will not make a return visit even if asked. In these cases, the opportunity to give the test result and to counsel the client on the basis of the test result will be lost (Department of Health, Cape Town, South Africa 2002). As services become more efficient, and the stigma around testing is reduced and prevention messages are successful, VCT clinics are seeing clients who are interested in knowing their ongoing HIV status return for regular testing visits.

**PREVENTION OF MOTHER-TO-CHILD TRANSMISSION**

HIV testing of pregnant women allows them to learn their own sero-status. Women who test positive can take appropriate steps to reduce the probability of passing HIV to their child during childbirth and breastfeeding. Without intervention, there is a 15–30 percent risk of mother-to-child transmission (MTCT) during pregnancy and delivery, as well as an additional 10–20 percent risk of MTCT through breastfeeding. In some countries, HIV testing for PMTCT is voluntary (“opt-in”). In those cases, the percentage of pregnant women who seek testing must be considered as part of the quantification formula. In other countries, testing is included as a core service (“opt-out”), and the number of pregnant women tested will be 100 percent of antenatal care clinic attendance. PMTCT testing programs should have pre-testing and post-testing counseling components.

**TESTING OF HIV-EXPOSED BABIES**

All babies born to HIV-positive mothers have the HIV antibodies passed from the mother, but they may not, in fact, be infected themselves. Until the mother’s antibodies clear at 18 months, or perhaps as early as 9 months, it is not possible to test for the virus itself using currently available HIV tests, except by use of polymerase chain reaction (PCR) tests. PCR testing is not routinely available in clinical settings, so a baby’s status often cannot be determined at birth. However, all HIV-exposed babies can be tested using rapid HIV tests to at least identify babies who are not infected. The benefit of using HIV tests would be to prevent HIV infection in babies who are negative at birth, because babies can also contract an HIV infection from an HIV-infected mother’s breast milk.

**HIV COUNSELING AND TESTING**

Some policymakers and members of the global community are moving toward a policy shift that considers it a basic human right for an individual to know his or her HIV status. A specific recommendation, with implications for supply chain management, would be that testing be provider-initiated rather than client-initiated, thereby resulting in service providers routinely offering testing and in clients choosing to opt out (as opposed to the current paradigm that requires a client to volunteer for a test). This approach to HIV diagnosis and clinic care management is encouraged in specialized settings, including in antenatal care, in TB and STI clinics, and in clinic and community-based health service settings. Provider-initiated HCT is a relatively new phenomenon and has replaced the practice of providers testing for clinical diagnosis without counseling the client.

Quantification for HCT will yield a higher number of tests because 100 percent of clients will be receiving counseling and will be offered testing. Although not all clients will accept testing, evidence from PMTCT programs that have chosen to implement “opt-out” testing suggests that more than 80 percent of clients will opt for testing after receiving counseling.
SENTINEL SURVEILLANCE (SS)
HIV testing is conducted on select population subgroups to enable health officials to describe the HIV/AIDS epidemic in a country, to plan and advocate for responses, and to evaluate the effectiveness of the responses.

Countries with generalized epidemics conduct sero-surveillance primarily among pregnant women at antenatal clinics as the basis of their surveillance system. Countries with concentrated epidemics or low-level epidemics focus primarily on specific population groups that are perceived to be at high risk for infection, for example, female sex workers and their clients, injecting drug users, or men who have sex with men. (WHO 2001)

Sentinel surveillance testing can be linked (i.e., the people tested are informed of the test results), or sentinel surveillance testing can be unlinked (i.e., the people tested are not informed of the test results).

OTHER USES
This category includes training and special studies (e.g., Demographic and Health Survey). It could also include the large-scale institutional testing of special populations such as military, police, prisoners, and so on, who may not necessarily go to traditional VCT or clinical sites.

HIV TESTING PROTOCOLS
Most established HIV/AIDS programs have defined testing protocols or protocols for each of the primary uses of HIV tests. The testing protocols are a guide for the individuals who are administering the tests. The protocols vary according to the HIV prevalence, the purpose of testing, and the number of different tests available in the program. Testing may be serial or parallel, and the testing protocol also depends on HIV prevalence, purpose of testing, and availability of tests.

Table 2 and 3 show examples of serial and parallel testing protocols. There are three different testing strategies for the serial (S) and the parallel (P) protocols.

TABLE 2. SERIAL PROTOCOLS

<table>
<thead>
<tr>
<th>Protocol</th>
<th>Tests</th>
<th>If, then</th>
<th>Examples</th>
</tr>
</thead>
</table>
| S1       | A     | If test A is positive, the result is positive.  
 if test A is negative, the result is negative. | Unlinked Blood Safety Program |
|          |       |          |          |
| S2       | A     | If test A is positive, run test B.  
 if test B is positive, the result is positive. | PMTCT or VCT program, with third test referral to the higher level |
|          | B     |          |          |
| S3       | A     | If test A is positive, run test B.  
 if test B is positive, the result is positive.  
 if test B is negative, run test C.  
 if test C is positive, the result is positive.  
 if test C is negative, the result is negative. | PMTCT or VCT program, all testing on site |
|          | B     |          |          |
|          | C     |          |          |
### TABLE 3. PARALLEL PROTOCOLS

<table>
<thead>
<tr>
<th>Protocol</th>
<th>Tests</th>
<th>If, then</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>P1</strong></td>
<td>AB</td>
<td>If tests A and B are both negative, the result is negative.</td>
<td>PMTCT or VCT program</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If tests A and B are both positive, the result is positive.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>If tests A and B are discordant, run test C.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>If test C is positive, the result is positive.</td>
<td></td>
</tr>
<tr>
<td><strong>P2</strong></td>
<td>A</td>
<td>If test A is negative, the result is negative.</td>
<td>Mobile clinic, with referral to the health center</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If test A is positive, run tests B and C in parallel.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BC</td>
<td>If one or both of tests B and C are positive, the result is positive.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>If tests B and C are both negative, the result is negative.</td>
<td></td>
</tr>
<tr>
<td><strong>P3</strong></td>
<td>AB</td>
<td>If tests A and B are both negative, the result is negative.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>If tests A and B are both positive, the result is positive.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>If tests A and B are discordant, run tests C and D in parallel.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CD</td>
<td>If tests C and D are both negative, the result is negative.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>If tests C and D are both positive, the result is positive.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>If tests C and D are discordant, the results are inconclusive.</td>
<td></td>
</tr>
</tbody>
</table>

If protocol S3, or protocol P1, or protocol P3 is being used in the program, the person doing the quantification must determine the average discordance rate between all brands of test A and all brands of test B. Those discordance rates become the basis for determining the number of tiebreaker tests required.
STEPS IN THE QUANTIFICATION

The following approach to quantification is based on the experience of DELIVER advisors in conducting HIV test quantifications in many of the 12 countries identified at the beginning of the guide. The challenges and lessons learned from this experience have been incorporated into the step-by-step approach to quantification presented here.

The quantification exercise should be conducted as a consultative process in collaboration with HIV testing stakeholders, including policymakers, program managers, and service providers, as well as laboratory, clinical, and procurement experts. The results of the quantification may be used to explain product selection, to describe policy and technical decisions, and to facilitate mobilization and allocation of financial resources for procurement of HIV tests.

Given that many countries are in various stages of expanding HIV/AIDS services, the quantification should be reviewed and updated at least every six months to reflect (a) actual program performance, (b) changes in policy or changes in testing and diagnostic practices, and (c) changes in patient behavior when seeking HIV counseling and testing services. The quantification should be reviewed as well to take advantage of new HIV testing technology and reduced prices.

PREREQUISITES TO QUANTIFICATION

The purpose and scope of a quantification, and the amount of data available that can be used, will vary from program to program. Prior to beginning the quantification process, it is critical to ensure that these prerequisites are as clear and well-defined as possible. Investing time at this stage in the process will help lay the foundation for effective, long-term forecasting.

DEFINE THE SCOPE AND THE PURPOSE OF THE QUANTIFICATION

The scope of the quantification will depend on various political, programmatic, financial, and environmental factors. For HIV tests, two initial factors that will help define the scope include (a) the purposes of use to be included, and (b) whether or not the quantification is for the whole country or for one sector. National-level quantifications are often a useful starting point, but separate quantifications may be needed for different sectors, programs, target populations, geographic regions, funding sources, or supply chains. The number, type, and level of the facilities to be covered by the quantification should also be defined.

Some examples of different scopes for quantifications that have been conducted include the following:

- National-level quantification across all purposes of use to meet the needs of the whole country
- Quantifications by different sector (public sector, nongovernmental [NGO] organizations, or private sector), for the same or different purposes of use
- Quantifications by program or by purpose of use (e.g., a quantification for HIV test requirements for the public sector VCT and PMTCT programs, or for VCT in the NGO and Mission sector only)
- Quantifications by target population (e.g., to support VCT for marginalized population groups, such as intravenous drug users or commercial sex workers)
• Quantifications by geographic region (e.g., HIV counseling and testing services may exist or may be supported in certain regions of the country and not in other regions)

• Quantifications by funding source (government or donor organizations that procure different products may require separate quantifications)

• Quantifications by supply chain (quantification for products that may be supplied by a particular source with its own procurement and distribution systems)

The purpose of the quantification must be identified. The following are examples:

• Is the quantification for resource mobilization in order to inform donors about funding requirements and to advocate for resources for HIV test kit procurement?

• Is the quantification for planning purposes in order to estimate national HIV test kit requirements and to assess the stock status of the in-country supply pipeline so that supply imbalances can be identified and corrected?

• Is the quantification to support an estimate of commodity procurement, storage, and distribution costs?

The quantification should answer the following key questions:

• How many patients can be tested with available funds? Or, conversely, how much would it cost to test a target number of patients within a given time period?

• How long will current stocks last, given current consumption and expected rates of growth?

• What quantities of HIV tests need to be procured, and when are the quantities needed to avoid stockouts and to support program expansion?

DESCRIBE THE PROGRAM

Before one begins the actual HIV test quantification, it is important to clearly define the programs for which commodities are being quantified. For HIV testing, given the fact that there are multiple purposes of use, the definition must include not only the program but also the purposes for which HIV tests are required.

From a logistics perspective, a program consists of all the HIV testing activities that have a common distribution pipeline. The HIV tests can be provided from the same funding source or from different funding sources, but if they all go into the same distribution pipeline, the HIV tests are used by one program and require one quantification.

Conversely, the HIV test kits can be provided from one funding source or from separate funding sources, but if they are distributed through separate distribution pipelines (e.g., through the Ministry of Health [MOH] distribution system and the Mission sector distribution system), each of those pipelines is considered a different program. A separate quantification must be conducted for each program, because supply chain factors such as lead time, buffer stock, and pipeline length vary by program.

DETERMINE THE PERIOD OF THE DEMAND FORECAST

Medium-term forecasts of HIV test requirements for two to five years are recommended to assist in program planning and in mobilizing financial resources for procurement of HIV tests to support program expansion. The quantification and the costing of commodity requirements for procurement with available funds for a one-year period are recommended for short-term procurement planning and should include specific quanti-
In country X in the public sector, the funds for test kits for blood safety are provided by the government using a Global Fund grant; the funds for test kits for VCT and PMTCT are provided both by the government Global Fund grant and by the President’s Emergency Plan for AIDS Relief (PEPFAR); and the funds for test kits for sentinel surveillance (SS) are provided by PEPFAR through the Centers for Disease Control and Prevention (CDC). However, all the kits are stored and distributed through the public sector’s MOH supply chain as part of the national HIV/AIDS program. In this case, you would forecast demand separately for each of those four purposes and then would aggregate the overall quantities required to determine the total quantities of kits required by the MOH.

In country Y, you are asked to conduct quantification for the blood safety, VCT, and SS activities. As you begin your questioning, you discover that the VCT and SS program HIV tests are procured through the MOH Public Health Unit and MOH Logistics Unit, and those tests are distributed through the MOH’s regular distribution system for essential drugs. The tests for blood safety are donated by an NGO, are briefly stored, and are then distributed separately to the government’s blood collection sites by a private distributor under contract to the NGO. Those are two separate programs, and they would require separate quantification exercises. However, within the MOH system, the first step in preparing the overall quantification is that demand for VCT and SS must be forecasted separately, before final quantities required can be aggregated.

DETERMINE THE TARGET NUMBER OF CLIENTS TO RECEIVE HIV COUNSELING AND TESTING FOR THE FORECAST PERIOD

Although targets based on population and HIV prevalence data alone may be useful for advocacy or resource mobilization, they should not be used for procurement planning. Those targets tend to highly overestimate commodity requirements because they are not based (a) on any actual services provided or commodities used, (b) on an assessment of realistic service delivery capacity or supply chain capacity, or (c) on resources available to support program growth.

Nationally accepted program targets that are based on population and HIV prevalence data should be reviewed and modified on the basis of previous assessments, evidence, or considerations of national- and facility-level readiness or capacity to provide HIV testing services and to manage the HIV test supply chain. Realistic client target numbers should be based on the following:

- Current level of service provision (number of sites with trained and sufficient providers, infrastructure, and laboratory services) and plans for expansion
- Current status of HIV test supply and product availability at HIV testing sites (stock status assessment of months of stock on hand at the facility and at the national level)
- Plans for financing and procurement of HIV tests (sources and amounts of funding available for procurement, funding disbursement schedules, procurement mechanisms, and respective lead times)
COLLECT THE REQUIRED DATA

Key data and information must be collected on HIV testing program activities, testing protocols, expected rates of change in client testing, and status of the HIV test supply in order to undertake the quantification. Collecting the data required to complete the quantification will probably be the most time-consuming and difficult of all the steps in the quantification process. In many cases, the required data may not be available. If one is to proceed with the quantification in cases where key data are not available or where key data are of very poor quality, it may be necessary to make estimates based on information gathered from key informants.

The following steps may be useful as a guide:

Step 1. Identify the type of program (e.g., MOH, nongovernmental organization, Mission, or religious, or pilot or research).

Step 2. List all HIV testing services provided or those services relevant for the quantification (HCT, PMTCT, VCT, BS, SS).

Step 3. Describe the model of care (the level and type of facilities where HIV testing services are provided such as a primary, secondary, tertiary, community-based, or outreach facility). Describing how the testing services are structured is a particularly important step for HIV test quantification, given the potential overlap in use of tests between various services. Questions that will provide general background information for defining the structure of services are listed in more detail in appendix A.

Step 4. Ascertain national guidelines for each HIV testing service identified, including recommended testing protocols or required standard testing protocols.

Step 5. Verify that all HIV tests required in the standard testing protocols are approved and registered for importation and for use in the country.

Step 6. Identify suppliers for each HIV test kit.

For HIV test kit financing and pricing information, the following steps are necessary:

Step 1. Identify all sources of financing for HIV tests (the government, international donor agencies, foundations, and pharmaceutical company donation programs such as Abbott’s Determine®).

Step 2. Determine the amount and duration of each financial commitment for HIV test kit procurement. Identify specifically when funds will be available for use.

Step 3. Identify the procurement mechanisms and suppliers for each product (national bulk procurement, procurement through local distributors, or direct donation of product).

Step 4. Verify local and international pricing information for each type of test kit.

Step 5. Identify any cost-recovery or cost-sharing mechanisms in effect. Are there any costs associated with HIV testing services (co-pay, free, sliding fee, partial subsidy)? What are the likely implications of the costs on client uptake of testing services?

Step 6. Identify any restrictions on financing regarding the types of tests that can be procured (for example, funds from the Global Fund to Fight AIDS, Tuberculosis, and Malaria might used only to procure HIV tests from WHO pre-qualified suppliers, but PEPFAR funds might only allow for HIV tests to be procured from an approved FDA or CDC list).
Step 7. Verify flexibility in amounts and in availability of funding (for example, are there potential funds that can be reallocated for procurement of HIV tests, and how long would reallocation take?)

For logistics data and supply chain information, here are the steps:

Step 1. Obtain national- and facility-level logistics data on HIV test use by purpose, by losses and adjustments, and by stock on hand, if available.

Step 2. Calculate the wastage rate of HIV tests caused by expiration, by loss, or by damage of the products. Without data, this rate is currently assumed to be 5–10 percent until data from stock cards become available.

Step 3. Determine whether an inventory control system is in place for management of HIV tests.

Step 4. For each procurement source, determine procurement lead times and supplier schedules and lead times for delivery of product.

Step 5. Determine established buffer stock levels or maximum and minimum inventory levels, if available.

Step 6. Confirm facility order intervals.

Step 7. Determine the frequency and timing of procurement procedures.

Sources of Data. The likely sources for much of the data needed for HIV test requirements quantification are key informants and program documents in-country.

Key informants to interview include the following:

• Head of the National AIDS Control Program NACP (usually within the MOH)

• Heads of the various HIV testing program services, including national laboratory services, blood safety services and transfusion services, VCT and PMTCT services, national hospital services, tertiary care hospitals, local blood collection facilities (in decentralized environments), etc.

• Head of the National AIDS Committee

• Service providers from NGOs providing HIV counseling and testing services

• Donors involved in HIV/AIDS support

• Procurement agents

• Service providers involved in VCT, PMTCT, SS, blood collection, and blood transfusions

• Private sector suppliers and laboratories

Program documents that are likely to provide useful information include the following:

• National HIV/AIDS policy or strategy papers

• National HIV testing, VCT, PMTCT, or Blood Safety Guidelines

• MOH or NACP annual reports or plans

• Budgetary documents or proposals, including those documents or proposals for the Global Fund, the World Bank, and PEPFAR
• Demographic and Health Surveys (which increasingly include useful information on provision and on use of HIV testing services)
• National essential drugs lists, particularly for laboratory reagents, for supplies, and for materials
• HIV testing protocols
• Health management information system (HMIS) reports
• Logistics records and reports on HIV test kit procurement, distribution, consumption, and balances
• Special reports, as well as studies from other cooperating agencies and from donors.

Useful Outputs. An extremely useful, visual output can be developed during or after the data collection process. That output is an HIV test flow map for each program or purpose of use that shows the suppliers (funding sources) of the test kits, the products supplied, and the general distribution flow of the test kits from suppliers to points of use. Also useful to include in the flow map is a depiction of records and reports at each level, as well as the flow of information and reports up and down the system. Documenting the results of the data collection (and defining the program) will avoid double-counting of some HIV test requirements and the failure to include other HIV test requirements.

FORECAST DEMAND
In this step of the quantification process, you forecast demand and then adjust for quality control, wastage, and service capacity to determine the adjusted demand. Tables 1–7 in appendix C present the information that must be collected for forecasting the adjusted demand for each of the six uses of HIV tests.

If quantifying by using ProQ Software, the three methodologies mentioned earlier are structured according to the type of data used. Appendix B at the end of this guide provides more detail, including an explanation of how each methodology can be applied to quantifying the different purposes of HIV testing. It is highly recommended that more than one of the three available methodologies be used for forecasting demand for each use of HIV tests. The results obtained should then be compared and should be reconciled by program managers.

Forecasting demand can be done as soon as the program has been defined and the information from tables 1–7 has been compiled. It is important to remember that all of the initial steps refer to forecasting demand for individual tests (to test one sample) rather than the entire kit. All of the calculations in this guide use individual tests as the unit, until the end of the process when the numbers of tests will be converted into the numbers of kits.

ADJUST DEMAND FOR QUALITY CONTROL
Some HIV tests require that additional tests be conducted to ensure the quality of the tests and of the testing procedure. The number of tests required for quality control is a percentage of the total number of tests conducted. This factor varies among brands of tests and should be described in program testing or laboratory guidelines. Some brands of tests have an internal control feature and do not require additional tests.

ADJUST DEMAND FOR WASTAGE
To fill the pipeline and to ensure a full supply of HIV tests, it is important to adjust the demand to compensate for tests that will not reach the service delivery point. The wastage factor is the estimated percentage of a
brand of test that will become damaged, be unusable, be spilt, or be found defective. Also, if provider-initiated
HCT is not a defined and acceptable purpose of use within the program, the wastage factor for the other
purposes might have to be increased because tests intended for uses such as VCT, PMTCT, blood safety, or SS
might be diverted to this kind of HCT.

If a forecasting methodology other than consumption-based methodology is used, one should adjust the
resulting demand for quality control and for wastage of tests. To adjust for quality control and for wastage, use
the following calculation:

\[
\text{Demand adjusted for quality control and wastage} = (\text{Demand}) \times [1 + (\text{quality control factor} + \text{wastage factor})]
\]

A 5–10 percent wastage factor should be used as the default value if actual wastage factors are not known or
cannot be accurately estimated. In the absence of data, the percentage value should be determined on the basis
of consultation with service providers for that purpose of use.

**DETERMINE HIV TESTING CAPACITY AND ADJUST DEMAND, IF NECESSARY**

After one adjusts forecasted demand for quality control and wastage, the program’s HIV testing capacity must
be measured for each purpose of use of HIV tests. HIV counseling and testing capacity are affected by skill
levels of staff members, staff availability, availability of HIV test kits and related supplies, and availability of
functioning equipment for tests requiring use of equipment.

The answers to the service capacity questions in tables 1–7 in appendix C can be used to determine the HIV
counseling and testing capacity for each purpose of use of HIV tests. The counseling capacity measure is
relevant for VCT, PMTCT, and testing of HIV-exposed babies. It may also be relevant for blood safety and SS
if those programs do linked testing.

If reliable service capacity data are not available,
testing statistics for a recent past period can be
discussed with key informants in order to arrive
at a projected testing capacity for the program
to be used for the quantification. If ELISA tests
are used, the availability of functioning testing
machines will also be part of the testing capacity
measure, as will the availability of qualified
technicians trained to use the ELISA machines.

If the forecasted demand figures are higher than the HIV testing capacity and if the HIV testing capacity
cannot be significantly increased, the forecasted demand figures should be adjusted downward to a level
commensurate with testing capacity, in consultation with decision makers.

The quantity resulting after the forecasted demand is adjusted for quality control, wastage, and service capac-
ity is referred to as the adjusted demand.
ESTIMATE REQUIREMENTS

After calculating the adjusted demand, it is necessary to estimate the quantities of HIV tests actually required both to meet the adjusted demand and to fill the pipeline to ensure a continuous supply to clients.

To estimate quantities required, obtain answers to the following questions:

1. What is the average monthly adjusted demand for each brand of test?

2. What is the average lead time in months for each brand of HIV test to be used in the program? (Lead time is defined as the time from when an order is placed until the tests arrive and are available for use. If the test kits are being imported, be sure to include time for customs clearance and inspection, as well as for quality check if the kits are to be assessed before being released for use.)

3. What is the desired level of buffer stock in months for each brand of test?

4. What is the volume of each brand of HIV test kit to be stored and distributed?

5. Which of the HIV test kits requires cold storage?

6. What is the volume of available cold storage and room temperature storage space at the level at which the HIV tests will enter the program?

7. What is the likely number of shipments of each brand of HIV test per year?

8. How much usable stock of each brand of HIV test is on hand at all levels of the system? (Subtract the number of tests on hand that will likely expire before use at current usage rates from the stock-on-hand figure.)

9. What quantity of each brand of HIV test is already on order from the suppliers? (Subtract the number of tests on order that will likely expire before use at current usage rates from the stock-on-order figure.)

The following calculations are used to estimate quantities required:

a. \[
\frac{\text{(Adjusted demand quantity for each brand of HIV test for one year)}}{12 \text{ months}} = \text{average monthly adjusted demand (AMAD) for each brand of HIV test.}
\]

b. \[
\text{(Desired buffer stock for each brand of HIV test in months)} \times \text{(AMAD for each brand of HIV test)} = \text{buffer stock for each brand of test.}
\]

c. \[
\text{(Adjusted demand quantity for each brand of HIV test for one year)} + \text{(buffer stock for each brand of test)} = \text{Quantities Required.}
\]

Note: Because of the short shelf life of most HIV test kits, lead times must be kept very short, and buffer stocks must be kept at the minimum possible levels. No separate calculation is made for desired end-of-year stock because it is assumed to be covered by the lead time and by the buffer stock allowances.

Calculations for Storage and Distribution Space Requirements. At some point during the quantification, additional adjustments in the requirements estimate may be required to adjust for the volume of product that can be adequately stored and distributed to ensure the quality and security of the HIV test supply. This adjustment does not always have to occur at this point and can also take place during procurement planning and shipment scheduling. However, it is very important that a calculation is made for the cool (2–8°C) storage space and room temperature (8–30°C) storage space requirements for the HIV tests that will be procured.
The volume of incoming shipments can be calculated using DELIVER’s *HIV Test Fact Sheets* (2006) or other sources of information on packaging and shipment sizes of HIV test kits on the market. Volumes can then be compared to actual storage space that is available in the country, especially at the point at which the test kits will enter the supply chain. The estimates of shipment volume and storage capacity are particularly important for products that require refrigeration, because that space is often at a premium.

Calculating storage space requirements entails the following steps:

a. To calculate the quantity for each brand of test:

\[
(\text{adjusted demand}) + (\text{lead time stock}) + (\text{buffer stock})
- (\text{usable stock on hand at all levels of the program}) - (\text{usable stock on order})
= \text{quantity required.}
\]

b. To calculate the volume at entry level for each brand of test:

\[
(\text{quantity required for each brand}) \times (\text{number of each brand of tests in a kit})
\times (\text{volume of one HIV test kit of each brand required})
= \text{total volume for each brand of HIV test.}
\]

c. To calculate the cold storage requirement at entry level for each brand of test:

\[
(\text{Volume of brand1 test requiring cold storage}
+ \text{volume of brand2 test requiring cold storage}
+ \text{volume of brand3 test requiring cold storage})
\times (\text{estimated number of shipments for the year of tests requiring cold storage})
= \text{cold storage requirement for HIV tests at the entry level.}
\]

d. To calculate the room temperature storage requirement at entry level for each brand:

\[
(\text{Volume of brand1 test requiring room temperature storage}
+ \text{volume of brand2 test requiring room temperature storage}
+ \text{volume of brand3 test requiring room temperature storage})
\times (\text{estimated number of shipments for the year of tests requiring room temperature storage})
= \text{room temperature storage requirement for HIV tests at the entry level.}
\]

e. Compare the volume per shipment of tests requiring cold storage and tests requiring under 30°C to the available cold storage space of both types.

f. If the available cold storage space and the available under 30°C storage space are the same as or larger than the expected shipment volumes, storage at entry level does not pose a constraint.

g. If the available cold storage space or the available under 30°C storage space is less than the volume of each shipment, advise the program managers that the storage space or the number of shipments must be increased so that each shipment can be properly stored on arrival.

Advisors or individuals who are engaged in preparing the quantification are strongly advised to verify as part of the process that adequate security measures exist for the volume of HIV tests that are to be stored and distributed at the different levels of the program and at HIV counseling and testing service sites. Adequate security measures will minimize obstacles once the products arrive in country.
ESTIMATE COSTS
To calculate financial requirements for the quantities of tests required, the following information is needed:

- What is the estimated cost per test kit of each brand of kit?
- What is the estimated cost for freight and insurance for the required volume and for the value of HIV tests if freight and insurance costs are not already included in the cost per test kit?
- What are the estimated customs duties and clearance costs for the required volume and value of HIV tests?
- What are the direct storage and distribution costs on this volume and value of HIV tests?

To estimate the cost of the total numbers of HIV tests required, the following steps should be followed:

- Divide the required quantity of each brand of test by the number of tests per kit for that brand of test to determine the number of test kits required.
- Discuss the estimated cost with key informants and review past purchase records to determine the likely cost per kit for each brand of kit.

To determine the estimated cost per kit, consult standard price references, *Sources and Prices of Selected Drugs and Diagnostics for People Living with HIV/AIDS* (WHO et al. 2003).

- Multiply the cost per kit by the number of kits for each brand to determine the total cost for each brand of test kit.
- Add all the preceding totals to determine the grand total of the financial requirement for all HIV tests for the year for the program. (Be cautious when you estimate the prices of test kits for the quantification. It is best to use a range of prices because often it is not known what prices will actually be obtained when the kits are procured.)
- Determine the cost of insurance and freight for this volume and value of kits, if applicable.
- Determine the costs of customs duties and customs clearance for this volume and value of HIV tests, and add this amount to the financial requirements.
- Determine any direct storage and distribution costs on this volume and value of HIV tests, and add this amount to the financial requirements.

It is important to consider the insurance and freight costs, customs-related costs, and direct storage and distribution costs at the quantification stage. Considering those costs will ensure that program managers are aware of the costs and that they can make provisions for them before the arrival of the HIV tests into the program. If those costs are not budgeted for in advance, there is a danger of the tests being delayed in customs clearance and in the distribution pipeline, thereby risking the loss of product through expiration.

DETERMINE QUANTITY TO PROCURE
The amount of funding available for procurement of HIV tests often is a deciding factor in determining the final decision on the quantities to procure.

- If sufficient funding is available, the final quantity to procure of each HIV test kit will be the same as the requirements estimate. In the current environment of increasing financial resources for HIV/AIDS commodity procurement, funding may be adequate to ensure full supply for the estimates of HIV test
requirements, provided that service delivery and supply chain capacity exist. Financial resources could also surpass program capacity to expand quality HIV counseling and testing services and to ensure a reliable supply of HIV tests. In that case, additional quantities of HIV tests should not be procured because such procurement in excess of system capacities may result in loss of product through overstocking and expiration.

- In situations where the cost estimate for procurement exceeds the available funding, program managers should use the results of the quantification and requirements estimate to mobilize resources to fill the gap. Experience has shown that program managers can be effective in advocating for increased funding if a quantifiable gap in quantities and in funds can be demonstrated, and if the calculations are based on quality data, informed assumptions, and a systematic approach to quantification.

- If further resources are not available, an adjustment has to be made to the requirements estimation. The method for how this adjustment should be done will vary by country and by program. At the very least, this process will require program managers to make decisions on the priorities for HIV testing for various uses to determine the quantities to procure. In situations of non-full supply of HIV test kits, the budget reconciliation step typically involves setting priorities for the purposes (e.g., Blood Safety, VCT, PMTCT, SS, HCT), and priorities for other uses for the kits and for the reduction of quantities to be procured to fit available funds. The budget reconciliation step could also involve revisiting previous decisions regarding protocol. But regardless of which decisions are made when setting priorities, a basic standard to uphold is that test kits should be procured in the proper proportion to ensure that the protocol can be completed.

- In other situations, the purpose of the quantification may be to determine how many clients can be tested for a year, given a specific amount of funding available. In that case, the cost of testing a specific number of clients (e.g., cost per client or cost per 1,000 clients) can be quantified for and then matched against available funding to determine the total number of clients who could receive HIV testing within the year.

After the quantities to procure have been determined for the period of the forecast, a shipment schedule should be developed. Because of the uncertainties described previously and the short shelf lives of many HIV tests, a flexible shipment schedule is recommended—often with quarterly shipments—in which shipment quantities can be adjusted to respond to client uptake of testing services, of existing stock levels, and of use rates of HIV tests. Agreements with suppliers may also need to include flexibility in delaying shipments of the annual quantities procured into the year following the year of the forecast if uptake of services does not meet expected demand.
All the steps described in the guide correspond to standard quantification methodologies, but they are organized so that the ProQ quantification software package can be used to perform all the calculations. Forecasting demand for HIV tests is complicated by the multiple purposes that HIV tests are used for, varying methodologies that can be used to forecast demand, and the large number of brands of tests that might be available or that might be used in a program.

Although DELIVER initially used Excel spreadsheets to quantify HIV test requirements, it soon became clear that the spreadsheets required extremely skilled users, and thus the ProQ software was developed. Although ProQ cannot be used in programs that do not have standard testing protocols, the software greatly simplifies calculations required to quantify requirements for HIV tests and has been used in multiple country programs for some or all purposes of use.

Complementing the ProQ software package is the PipeLine software, which can be used for procurement planning after the quantification is complete. PipeLine can be used to plan and to adjust shipment quantities and delivery schedules and to identify funding needs for procurement. PipeLine is also a useful tool for sharing results among stakeholders, because it produces reports and graphs on the status of scheduled shipments, past and projected consumption trends, and stock levels for each product in-country.
SUMMARY OF CHALLENGES AND LESSONS LEARNED IN QUANTIFICATION OF HIV TESTS

COMMON CHALLENGES
While preparing national-level HIV test quantifications in a number of countries, DELIVER identified a number of challenges that were common and that were consistent across the different countries. Those challenges are summarized below and were the key guiding principles in developing the approach to quantification presented in this guide.

- Data on HIV testing services and HIV test kit use are limited and, when available, are often unreliable or insufficient for use in quantifying HIV test requirements.
- Standard testing protocols may vary by purpose of testing (e.g., VCT, PMTCT, or Blood Safety) or by program (e.g., government-supported vs. donor-supported); may be in need of revision; or may not have been widely disseminated to providers.
- Program targets may not take into account neither service delivery capacity to increase HIV testing rates nor supply chain capacity to finance, procure, and manage greater volumes of HIV tests.
- Program targets for increasing HIV testing may not be linked to program targets for increasing ART patient enrollment.
- Program expansion does not occur as rapidly as expected.
- Multiple sources of funding, procurement mechanisms, and distribution channels are used for HIV tests.
- Quantification capacity at the country and at the program levels is limited.
- Communication and coordination are lacking among key stakeholders and implementers (i.e., policymakers, program managers, service providers, funding sources, procurement agents, and suppliers) on issues related to the selection, quantification, and procurement of HIV test needs.
- Quantification and procurement occur when funding becomes available, rather than as a program planning activity that identifies commodity needs and that mobilizes resources for procurement in a timely fashion. The lack of procurement planning has led to stockouts and to expensive emergency procurements.
- Global shortages of HIV tests related to limitations in supplier production capacity as a result of spikes in demand may need to be addressed in the quantification to identify alternate sources of supply for the required quantities of product. Similarly, while manufacturers of new HIV test kits may offer promising alternatives, they may not be able to respond to exponential increases in demand for their product in the short term.
USEFUL LESSONS
The following lessons learned from the DELIVER experience in conducting HIV test quantifications in these countries have also been incorporated into the approach to quantification that has been presented in this guide.

• The quantification exercise itself is time intensive and resource intensive. Therefore, adequate time, funding, and human resources with appropriate skills to conduct the quantification exercise should be planned and budgeted for.

• Quantifications that are currently based on informed assumptions will become more evidence-based over time as the availability and quality of data improve through strengthening of the LMIS.

• Quantification requires a consultative process with multiple stakeholders and implementers to explain the assumptions about the selection, quantification, and procurement of HIV tests.

• Convening one or more consultative stakeholder meetings throughout the quantification process is recommended to clarify and to review the data sources, assumptions, and methodologies used, as well as to reach consensus on commodity requirements and funding needs. Convening consultative stakeholder meetings can be a critical step toward transferring ownership of the results to in-country stakeholders. The consultative stakeholder meetings can also serve to facilitate resource mobilization, to clarify expectations, and to promote collaboration and coordination, especially in the event of disruptions in commodity supply, which may affect availability of products for customers at service delivery points.

• The quantification should be based on realistic program plans and on available financing.

• The results of the quantification should be used to determine specific order quantities and shipment schedules for short-term procurement planning that is based on available funding.

• The results of the quantification should also be used for medium- and long-term program planning and for resource mobilization for HIV testing services.

• The quantification should be reviewed and updated at least every three to six months, and procurement plans should be adjusted accordingly.

ADDITIONAL CONSIDERATIONS
The selection, procurement, storage, distribution, and end use of HIV tests are not covered in this guide. However, several points related to those activities are worth mentioning:

• All other technical factors being equal, preference in selection should be given to HIV tests that do not require cold storage, that have the longest shelf lives, and that are as self-contained with peripheral supplies as possible.

• The emphasis in procurement should be on developing supplier relationships that allow for frequent shipments of relatively small quantities of freshly manufactured kits. When possible, the purchasing contract should allow for accelerating or delaying the delivery of test kits to the program in response to the actual consumption of the test kits.

• The shipment schedule for the HIV test kits must reflect the lead time and shelf life for each product, as well as the current storage and distribution capacity of the logistics system. For example, tests with a short shelf life and cold chain storage requirements may have to be manufactured and shipped to a country at more frequent intervals than HIV test kits that have a longer shelf life and that can be stored at room
temperature. The in-country pipeline for those items would need to be shorter than for drugs and other supplies, and the test kits would need to be delivered to service delivery points more frequently.

- Because of their short shelf life, HIV test kits ideally should be distributed from the central level straight to the service delivery points with no intervening layers of storage, handling, or paperwork.
REFERENCES


APPENDIX A

BACKGROUND QUESTIONS TO DEFINE MODEL OF CARE AND THE STRUCTURE OF HIV TESTING SERVICES

QUESTIONS

BLOOD SAFETY

1. Is the testing protocol for blood safety the same throughout the country?
2. Is the testing protocol for blood safety the same in the government, nongovernmental organization (NGO), missionary, and private facilities?
3. Is the blood safety program centralized or decentralized?
4. How many sites collect donated blood?
5. Is blood collected at the transfusion site or elsewhere?
6. Where is blood tested: at collection site, blood bank, or transfusion site?
7. How many laboratories do blood screening?
8. Are there NGO, missionary, or private suppliers/testers of blood?
9. If yes, who supplies their HIV tests?
10. What brands and types of tests are used at what level in the program?

VOLUNTARY COUNSELING AND TESTING (VCT)

1. Is the testing protocol for VCT the same throughout the country?
2. Is the testing protocol for VCT the same in the government, NGO, missionary, and private facilities?
3. Is the VCT program centralized or decentralized?
4. How many VCT sites are there (sites with trained counselor and testing capacity)?
5. How many of these are government, NGO, and Mission sector sites?
6. Where is blood tested: at the VCT site or elsewhere?
7. Where are the VCT sites located?
8. Are there plans to open new VCT sites in the future? If yes, how many sites?
9. From where do the NGO and Mission sector VCT sites receive their HIV tests?
10. What brands and types of HIV tests are used at what levels in the program?

**PREVENTION OF MOTHER-TO-CHILD TRANSMISSION (PMTCT)**

1. Is the testing protocol for PMTCT the same throughout the country?
2. Is the testing protocol for PMTCT the same in the government, NGO, missionary, and private facilities?
3. Is the PMTCT program centralized or decentralized?
4. How many PMTCT sites are there?
5. How many of these are government, NGO, and Mission sector sites?
6. Where is blood tested: at the PMTCT site or elsewhere?
7. Where are the PMTCT sites located?
8. Are there plans to open new PMTCT sites in the future? If so, how many sites?
9. From where do the NGO and Mission sector sites receive their HIV tests?
10. What brands and types of HIV tests are used at what levels in the program?

**TESTING OF HIV-EXPOSED BABIES**

1. Is the testing protocol for HIV-exposed babies the same throughout the country?
2. Is the testing protocol for HIV-exposed babies the same in the government, NGO, missionary, and private facilities?
3. Is the HIV-exposed babies testing program centralized or decentralized?
4. Are HIV-exposed babies tested at antenatal care sites or at other health facilities?
5. How many testing sites are there for HIV-exposed babies?
6. How many of these are government, NGO, and Mission sector sites?
7. Where is blood tested: at the HIV-exposed babies testing site or elsewhere?
8. Where are the HIV-exposed babies testing sites located?
9. Are there plans to open new sites for testing HIV-exposed babies in the future? If so, how many sites?
10. From where do the NGO and Mission sector sites receive their HIV tests?
11. What brands and types of HIV tests are used at what levels in the program?
HIV COUNSELING AND TESTING (HCT)
1. Are AIDS patients routinely diagnosed through HCT?
2. What service statistics are available on the use of HIV tests for HCT?
3. Approximately how many and what types of sites conduct HIV testing for HCT?
4. What consumption data are available for HIV tests for HCT?
5. Is the testing protocol for HCT the same throughout the country?
6. Is the testing protocol for HCT the same in government, NGO, missionary, and private facilities?
7. From where do the NGO and Mission sector sites receive their HIV tests for HCT?
8. What brands and types of HIV tests are used at what levels in the program for HCT?

SENTINEL SURVEILLANCE
1. How many sentinel surveillance sites are there and of what type?
2. What is the sample size per sentinel surveillance site?
3. Where are sentinel surveillance site blood samples tested?
4. Is sentinel surveillance an ongoing, year-round activity, or is it for a limited time each year?
5. What brands and types of HIV tests are used for sentinel surveillance?
CONSUMPTION-BASED OR LOGISTICS METHODOLOGY
In this methodology, the forecast is based on stock consumption rates. This methodology is most useful in mature, stable testing programs that have a full supply of test kits and where reliable data are available. It is useful only in a system where prior consumption can be determined or at least extrapolated. One caution on using this methodology is that data on past consumption of HIV tests may not be predictive of future use because past testing was often undertaken on a pilot or small-scale basis, often by nongovernmental organizations. Also, if the program has experienced frequent stockouts of test kits, the consumption figures might be understated relative to what consumption would have been if the test kits had been available in full supply.

Question 1—Determine how many of each brand of test were used in the past 12 months for each of the seven uses of the tests. If there were frequent periods of stockouts of HIV tests, make an estimate of the number of tests that would have been consumed for these periods of stockouts. Add this number to the estimated number of tests used in the past year. This is possible if the program has a very well-designed and well-executed information system with reports that provide this information. This is likely to be the case in only the most mature and well-supported programs.

If this information is not available or is of questionable reliability, go to question 2.

Question 2—Examine records and reports, and discuss with key informants to determine which level of the health care system (e.g., service delivery point, district, provincial, or regional) has the most complete logistics records and reports for HIV tests.

Questions 3–6—For that level of the system, answer questions 3–6.

3. For this level of the logistic system, what was the beginning inventory for each brand of test at the start of the year?
4. For this level of the logistic system, what were the receipts for each brand of test for the year?
5. For this level of the logistic system, what were the losses and adjustments for each brand of test for the year? (Note: This includes any changes to the inventory records to reflect losses or transfers or to correct record keeping errors. It can be a positive or negative number.)
6. For this level of the logistic system, what was the ending inventory for each brand of test for the year?

Use the following calculation to calculate estimated consumption for each brand:

\[
\text{(Beginning inventory + receipts) } \pm \text{(losses/adjustments)} - \text{ ending inventory } = \text{ estimated consumption for the year.}
\]

Compare the consumption of tests in question 1 to the consumption resulting from the calculations in questions 3–6, and select the figure you wish to use for this quantification. Generally, you should select the consumption figure on the basis of what you perceive to be the most reliable data.
Question 7—Discuss with key informants the expected rate of change (increase or decrease) in use of HIV tests for the year you are quantifying. Take into account economic, political, and programmatic factors such as information campaigns, expansion of service networks, funding shortfalls, etc., that could raise or lower demand for HIV testing for the forecast period.

\[
\text{(The estimated consumption of each brand of test for the past year)} \times (1 + \text{the change factor in decimal form}) = \text{estimated demand for the year for which you are quantifying.}
\]

If the program experienced frequent stockouts of HIV test kits, how many days on average were facilities stocked out of HIV tests?

\[
\text{(Estimated consumption for the year)} + \text{(number of days the facilities had tests in stock)} \times \text{(number of days the facilities were stocked out of tests)} = \text{estimated number of tests that would have been consumed during periods of the stockout.}
\]

Add this number to the (estimated consumption for the year).

**MORBIDITY-BASED (DEMOGRAPHIC) METHODOLOGY**

In this methodology, the forecast is based on the population of the program service areas and the HIV prevalence rates in these areas. The morbidity-based (demographic) methodology is often used for new programs where little or no historical logistics or service statistics data are available.

**BLOOD SAFETY**

**Question 1**—Using a census or other records, estimate the population of the areas served by the blood transfusion centers and by hospitals that collect blood.

**Question 2**—Discuss with the blood transfusion services what percentage of the service area population will likely donate blood. Discuss with program managers, and come to an agreement on this figure.

**Question 3**—Discuss with key informants, and review records to obtain information on how many times a year a donor donates blood.

**Question 4**—Review records and reports of blood safety testing results to determine the HIV prevalence rate among blood donors. If the blood donor screening program is effective, this HIV prevalence rate should be significantly lower than the HIV prevalence rate in the general population.

**Question 5**—Discuss with key laboratory personnel and program managers the discordance rate between the screening and confirmatory HIV tests.

**Question 6**—Determine from published guidelines for blood safety, discussions with key informants, and field observations, which of the HIV testing protocols are used for blood safety.
If testing protocol S3 is in use, which is three tests conducted serially, demand for HIV tests would be calculated as follows:

\[
\text{(Population of the service area)} \times \left( \frac{\text{units of blood to be collected}}{\text{demand for HIV screening tests}} \right) \times \left( \frac{\text{Estimated units of blood to be collected}}{\text{demand for HIV screening tests}} \right) = \text{demand for HIV screening tests.}
\]

\[
\text{(Units of blood to be collected)} \times \left( \frac{\text{times per year that a donor donates blood}}{\text{demand for HIV screening tests}} \right) \times \left( \frac{\text{estimated units of blood to be collected}}{\text{demand for HIV screening tests}} \right) = \text{demand for HIV screening tests.}
\]

\[
\text{(Demand for HIV confirmatory tests)} \times \left( \frac{\text{blood donor HIV prevalence rate}}{\text{demand for HIV screening tests}} \right) \times \left( \frac{\text{estimated units of blood to be collected}}{\text{demand for HIV screening tests}} \right) = \text{demand for HIV tie-breaking tests.}
\]

If parallel testing protocol P1, which is two tests in parallel and one tie-breaking test for discordant results, is being used for blood safety, the demand for both tests A and B would equal the estimated units of blood to be collected. The demand for test C would equal the number of blood units collected times the discordance rate between tests A and B. Variations on this formula would apply to the other parallel testing protocols.

**VOLUNTARY COUNSELING AND TESTING (VCT)**

The demand for HIV tests for VCT under a S3 testing protocol would be as follows:

\[
\text{(Population of the service area)} \times \left( \frac{\text{estimated units of blood to be collected}}{\text{demand for HIV screening tests}} \right) \times \left( \frac{\text{demand for HIV screening tests}}{\text{demand for HIV screening tests}} \right) \times \left( \frac{\text{demand for HIV confirmatory tests}}{\text{demand for HIV screening tests}} \right) \times \left( \frac{\text{demand for HIV tie-breaking tests}}{\text{demand for HIV confirmatory tests}} \right) = \text{demand for HIV screening tests.}
\]

\[
\text{(Demand for HIV screening tests)} \times \left( \frac{\text{times per year that a donor donates blood}}{\text{demand for HIV screening tests}} \right) \times \left( \frac{\text{estimated units of blood to be collected}}{\text{demand for HIV screening tests}} \right) = \text{demand for HIV screening tests.}
\]

\[
\text{(Demand for HIV confirmatory tests)} \times \left( \frac{\text{blood donor HIV prevalence rate}}{\text{demand for HIV screening tests}} \right) \times \left( \frac{\text{estimated units of blood to be collected}}{\text{demand for HIV screening tests}} \right) = \text{demand for HIV tie-breaking tests.}
\]

As with blood safety, there would be variations on these quantities if parallel testing protocols were being used.

**PREVENTION OF MOTHER-TO-CHILD TRANSMISSION (PMTCT)**

The demand for HIV tests for PMTCT under the S3 testing protocol would be as follows:

\[
\text{(Women of reproductive age in PMTCT site service areas)} \times \left( \frac{\text{pregnancy rate in the service areas}}{\text{demand for HIV screening tests for PMTCT}} \right) \times \left( \frac{\text{estimated units of blood to be collected}}{\text{demand for HIV screening tests for PMTCT}} \right) \times \left( \frac{\text{demand for HIV screening tests for PMTCT}}{\text{demand for HIV screening tests for PMTCT}} \right) \times \left( \frac{\text{demand for HIV confirmatory tests}}{\text{demand for HIV screening tests for PMTCT}} \right) \times \left( \frac{\text{demand for HIV tie-breaking tests}}{\text{demand for HIV confirmatory tests}} \right) = \text{demand for HIV screening tests for PMTCT.}
\]

\[
\text{(Demand for HIV screening tests for PMTCT)} \times \left( \frac{\text{times per year that a donor donates blood}}{\text{demand for HIV screening tests for PMTCT}} \right) \times \left( \frac{\text{estimated units of blood to be collected}}{\text{demand for HIV screening tests for PMTCT}} \right) = \text{demand for HIV screening tests for PMTCT.}
\]

\[
\text{(Demand for HIV confirmatory tests)} \times \left( \frac{\text{blood donor HIV prevalence rate}}{\text{demand for HIV screening tests for PMTCT}} \right) \times \left( \frac{\text{estimated units of blood to be collected}}{\text{demand for HIV screening tests for PMTCT}} \right) = \text{demand for HIV tie-breaking tests.}
\]
(Demand for HIV confirmatory tests)  
\times (discordance rate between screening and confirmatory tests) = demand for HIV tie-breaking tests.

**TESTING OF HIV-EXPOSED BABIES**

The demand for HIV tests for testing HIV-exposed babies under the S3 testing protocol would be as follows:

\[
\begin{align*}
(A \times (\text{HIV prevalence rate of HIV-exposed babies}) & = B, \text{ demand for confirmatory tests for HIV-exposed babies tested at age 9 months.} \\
B \times (\text{discordance rate between screening and confirmatory tests}) & = C, \text{ demand for tie-breaker tests for HIV-exposed babies tested at age 9 months.} \\
B \times (\% \text{ of babies testing positive at age 9 months who will be brought for retesting at age 18 months}) & = D, \text{ demand for HIV screening tests for HIV-exposed babies tested at age 18 months.} \\
D \times (\text{HIV prevalence rate of HIV-exposed babies testing at age 18 months}) & = E, \text{ demand for HIV confirmatory tests for HIV-exposed babies testing at age 18 months.} \\
E \times (\text{discordance rate between the screening and confirmatory tests}) & = F, \text{ demand for tie-breaker tests for HIV-exposed babies tested at age 18 months.} \\
A + D & = \text{ total demand for screening tests for HIV-exposed babies for the year for which you are quantifying.} \\
B + E & = \text{ total demand for confirmatory tests for HIV-exposed babies for the year for which you are quantifying.} \\
C + F & = \text{ total demand for tie-breaker tests for HIV-exposed babies for the year for which you are quantifying.}
\end{align*}
\]

A very small additional quantity of tests would be required for retesting babies who were HIV-negative at the time of the 9- or 18-month test but who were still breastfeeding at that time or who had discontinued breastfeeding just shortly before being tested at age 9 or 18 months. These babies would be retested three months after being weaned from breast milk.

Because of the testing intervals of 9 months, not all the tests quantified using the above formula would be consumed in a one-year period. However, for quantification purposes, it is assumed that the quantities calculated would be consumed in one year. This assumption is made because testing of HIV-exposed babies from the previous year, because of the 9-month testing intervals, would spill over into the year for which you are quantifying, thereby offsetting the number of tests quantified for this year that will spill over into the following year.
HIV COUNSELING AND TESTING (HCT)

The demand for HIV tests for HCT under the S3 testing protocol would be as follows:

\[(\text{Population of clinic service areas}) \times (\% \text{ if population is likely to access program clinics}) \times (\% \text{ of population accessing program clinics who will show signs and symptoms of AIDS}) = \text{demand for HIV screening tests for HCT.}\]

\[(\text{Demand for HIV screening tests for HCT}) \times (\text{HIV prevalence rate among clinic patients}) \times (\text{discordance rate between screening and confirmatory tests}) = \text{demand for HIV confirmatory tests for HCT.}\]

\[(\text{Demand for HIV confirmatory tests for HCT}) \times (\text{HIV prevalence rate among blood donors}) \times (\text{discordance rate between screening and confirmatory tests}) = \text{demand for HIV tie-breaking tests for HCT.}\]

MORBIDITY-BASED (SERVICE STATISTICS) METHODOLOGY

This methodology is based on the projection of past levels of testing.

BLOOD SAFETY

**Question 1**—Determine from records and reports the approximate number of units of blood collected in the past year.

**Question 2**—If information is not available on units collected, then determine from records and reports the approximate number of units of blood transfused in the past year.

**Question 3**—Interview key informants in the blood transfusion services to determine the approximate discard rate of blood units collected.

To use the information gathered for questions 2 and 3 to estimate the number of blood units collected in the past year, divide the number of blood units transfused by \((1 - \text{the discard rate}) = \text{number of units collected.}\)

The demand for HIV tests for blood safety using testing protocol S3 is calculated as follows:

\[(\text{Units of blood collected in the past year}) \times (1 + \text{expected rate of change in blood collection}) = \text{units of blood to be collected in the forecast year}\]

\[(\text{Demand for HIV screening tests}) \times (\text{HIV prevalence rate among blood donors}) = \text{demand for HIV confirmatory tests for blood safety.}\]

\[(\text{Demand for HIV confirmatory tests for blood safety}) \times (\text{discordance rate between screening and confirmatory tests}) = \text{demand for HIV tie-breaking tests for blood safety.}\]
**VOLUNTARY COUNSELING AND TESTING**
Under protocol S3, the tests required for VCT would be calculated as follows:

\[
\text{Demand for HIV screening tests for VCT in the year for which you are quantifying} = \frac{\text{(VCT clients tested in the past year) \times (1 + \text{expected rate of change in VCT testing})}}{\text{(Demand for screening tests for VCT) \times (HIV prevalence rate among VCT clients) \times (Demand for HIV confirmatory tests for VCT) \times (Discordance rate between screening and confirmatory tests)}}
\]

**PREVENTION OF MOTHER-TO-CHILD TRANSMISSION**
The demand for HIV tests for PMTCT under testing protocol S3 is calculated as follows:

\[
\text{Demand for HIV screening tests for PMTCT} = \frac{\text{(Number of pregnant women who were tested for HIV in the past year in the PMTCT Program) \times (1 + \text{expected rate of change in PMTCT testing})}}{\text{(Demand for HIV screening tests for PMTCT) \times (HIV prevalence rate among PMTCT clients) \times (Demand for HIV confirmatory tests for PMTCT) \times (Discordance rate between screening and confirmatory tests)}}
\]

**TESTING OF HIV-EXPOSED BABIES AND OTHER USES**
Under testing protocol S3 the tests required for testing of HIV-exposed babies and for other uses would be calculated in the same manner as for VCT and PMTCT.

**TARGET METHODOLOGY**
This methodology is based not on the need for the tests in a population, but on the number of tests program managers believe are necessary (e.g., for sentinel surveillance, special studies, or training) or on the number of tests that program managers believe the program can conduct given the number of available staff and other resources. Under this methodology—

\[
\text{The number of clients or blood samples targeted} = \frac{\text{demand for HIV screening tests}}{\text{demand for HIV confirmatory tests}} = \frac{\text{(Demand for HIV screening tests) \times (HIV prevalence rate for the target group) \times (Demand for HIV confirmatory tests) \times (Discordance rate between screening and confirmatory tests)}}{\text{demand for HIV screening tests}}
\]

For sentinel surveillance, the World Health Organization’s protocol recommends only one test, so no confirmatory test is used. Some number or percentage of screening samples is randomly selected for quality control testing. If these quality control test results differ from the screening test results, further tests may be used for validation.
### TABLE 1. DATA REQUIRED TO FORECAST ADJUSTED DEMAND FOR HIV TESTS FOR BLOOD SAFETY

<table>
<thead>
<tr>
<th>Logistics</th>
<th>Demographic/Morbidity</th>
<th>Service Statistics</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How many of each brand of tests were consumed the past for blood safety?</td>
<td>1. What is the population of the catchment area covered by this blood safety program?</td>
<td>1. How many blood units were collected during the past year?</td>
<td>1. What is the targeted number of blood units to be collected in the year for which you are quantifying?</td>
</tr>
<tr>
<td>2. What is the lowest level of the system having relatively complete data?</td>
<td>2. What percentage of people in this population will donate blood?</td>
<td>2. How many blood units were transfused during the past year?</td>
<td>2. What is the HIV prevalence rate among blood donors?</td>
</tr>
<tr>
<td>3. For this level of the logistic system, what was the beginning inventory of each brand of test at the start of the year? For this level of the logistic system, what were the receipts for each brand of test for the year?</td>
<td>3. On average, how many times does a blood donor donate per year?</td>
<td>3. What percentage of blood units collected during the past year was discarded (include blood units discarded for testing positive for pathogens, expiry, and other reasons)?</td>
<td>3. What is the average discordance rate between the screening and confirmatory tests?</td>
</tr>
<tr>
<td>5. For this level of the logistic system, what were the expiries, losses, and adjustments for each brand of test for the year?</td>
<td>4. What is the HIV prevalence rate among blood donors?</td>
<td>4. What is the expected rate of change in blood collection in the year for which you are quantifying?</td>
<td>4. What is the HIV testing protocol for blood safety?</td>
</tr>
<tr>
<td>6. For this level of the logistic system, what was the ending inventory for the year?</td>
<td>5. What is the average discordance rate between the screening and confirmatory tests?</td>
<td>5. What is the HIV prevalence rate among blood donors?</td>
<td></td>
</tr>
<tr>
<td>7. What is the expected rate of change of HIV test consumption for blood safety for the year for which you are quantifying?</td>
<td>6. What is the HIV testing protocol for blood safety?</td>
<td>6. What is the average discordance rate between the screening and confirmatory tests?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>7. What is the HIV testing protocol for blood safety?</td>
<td>7. What is the HIV testing protocol for blood safety?</td>
<td></td>
</tr>
</tbody>
</table>

### Quality Control and Wastage Factors

1. What percentage of each brand of test will be used for quality control purposes?
2. What percentage of each brand of test will be wasted through expiry, faulty product, etc.?

### Service Capacity

1. For blood safety, what is the total number of technicians conducting HIV tests?
2. How many days a year, on average, will a technician conduct HIV tests for blood safety?
3. On average, how many HIV tests for blood safety will a technician conduct per day?
4. If reliable service capacity data are not available, discuss with key informants the testing capacity for blood safety. Using this information, determine the maximum number of tests that can be conducted for purposes of blood safety during the year for which you are quantifying.

If an ELISA/Blot is picked for the test selection—

5. What is the yearly laboratory machine capacity for conducting the HIV test indicated in the product selection?
### TABLE 2. DATA REQUIRED TO FORECAST ADJUSTED DEMAND FOR HIV TESTS FOR VOLUNTARY COUNSELING AND TESTING (VCT)

#### DEMAND

<table>
<thead>
<tr>
<th>Logistics</th>
<th>Demographic/Morbidity</th>
<th>Service Statistics</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How many of each brand of tests were consumed for VCT in the past year?</td>
<td>1. What is the total population of the catchment areas served by VCT sites?</td>
<td>1. For VCT, how many clients were tested during the past year?</td>
<td>1. What is the targeted number of VCT clients to be tested in the year you are quantifying?</td>
</tr>
<tr>
<td>2. What is the lowest level of the system having relatively complete data?</td>
<td>2. What percentage of the population in the catchment areas served by VCT sites is likely to come for counseling?</td>
<td>2. What is the HIV prevalence rate among the tested clients?</td>
<td>2. What is the HIV prevalence rate among VCT clients?</td>
</tr>
<tr>
<td>3. For this level of the logistic system, what was the beginning inventory for each brand of test at the start of the year?</td>
<td>3. What percentage of counseled clients is likely to request an HIV test?</td>
<td>3. What is the expected rate of change for VCT?</td>
<td>3. What is the average discordance rate between the screening and confirmatory tests?</td>
</tr>
<tr>
<td>4. For this level of the logistic system, what were the receipts for each brand of test for the year?</td>
<td>4. What is the HIV prevalence rate of VCT clients requesting an HIV test?</td>
<td>4. What is the average discordance rate between the screening and confirmatory tests?</td>
<td>4. What is the testing protocol for VCT?</td>
</tr>
<tr>
<td>5. For this level of the logistic system, what were the expiries, losses, and adjustments for each brand of test for the year?</td>
<td>5. What is the average discordance rate between the screening and confirmatory tests?</td>
<td>5. What is the testing protocol for VCT?</td>
<td></td>
</tr>
<tr>
<td>6. For this level of the logistic system, what was the ending inventory for each brand of test for the year?</td>
<td>6. What is the testing protocol for VCT?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. What is the expected rate of change of HIV test consumption for VCT in the year you are quantifying?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Quality Control and Wastage Factors

1. What percentage of each brand of test will be used for quality control purposes?
2. What percentage of each brand of test will be wasted through expiry, faulty product, etc.?

#### Service Capacity

1. For the VCT program, what is the total number of counselors?
2. How many days a year, on average, will a counselor do VCT?
3. Do counselors conduct HIV tests? YES □ NO □

If YES, proceed to question #4A. If NO, proceed to question #4B.
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>4A.</strong> On average, how many VCT clients per day will a counselor counsel if this same counselor is also conducting the tests?</td>
<td><strong>4B.</strong> On average, how many VCT clients per day will a counselor counsel if the counselor is not conducting the tests?</td>
</tr>
<tr>
<td><strong>5A.</strong> What percentage of counseled clients is likely to request HIV testing?</td>
<td><strong>5B.</strong> What percentage of counseled clients is likely to request HIV testing?</td>
</tr>
<tr>
<td><strong>6A.</strong> If reliable service capacity data are not available, discuss with key informants the counseling and testing capacity for VCT. Using this information, determine the maximum number of clients who can be tested in the VCT program during the year you are quantifying.</td>
<td><strong>6B.</strong> For the VCT program, what is the total number of technicians conducting HIV tests?</td>
</tr>
<tr>
<td><strong>7B.</strong> How many days a year, on average, will a technician conduct HIV tests for VCT?</td>
<td><strong>7B.</strong> How many days a year, on average, will a technician conduct HIV tests for VCT?</td>
</tr>
<tr>
<td><strong>8B.</strong> On average, how many HIV tests for VCT will a technician conduct per day?</td>
<td><strong>8B.</strong> On average, how many HIV tests for VCT will a technician conduct per day?</td>
</tr>
<tr>
<td><strong>9B.</strong> If reliable service capacity data is not available, discuss with key informants the testing capacity for VCT. Using this information, determine maximum number of clients who can be tested in the VCT program during the year you are quantifying.</td>
<td><strong>9B.</strong> If reliable service capacity data is not available, discuss with key informants the testing capacity for VCT. Using this information, determine maximum number of clients who can be tested in the VCT program during the year you are quantifying.</td>
</tr>
<tr>
<td>If an ELISA/Blot is picked for the test kit selection—</td>
<td></td>
</tr>
<tr>
<td><strong>10B.</strong> What is the yearly laboratory machine capacity for conducting the HIV test indicated in the product selection for VCT?</td>
<td></td>
</tr>
</tbody>
</table>
**Table 3. Data Required to Forecast Adjusted Demand for HIV Tests for Prevention of Mother-to-Child Transmission (PMTCT)**

**Demand**

<table>
<thead>
<tr>
<th>Logistics</th>
<th>Demographic/Morbidity</th>
<th>Service Statistics</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How many of each brand of tests were consumed during the past year for PMTCT?</td>
<td>1. How many women of reproductive age live in the catchment area of ANC sites offering PMTCT?</td>
<td>1. How many pregnant women were tested for HIV in sites offering PMTCT in the past year?</td>
<td>1. What is the targeted number of clients to be tested for PMTCT in the year for which you are quantifying?</td>
</tr>
<tr>
<td>2. What is the lowest level of the system having relatively complete data?</td>
<td>2. What is the pregnancy rate in the catchment area?</td>
<td>2. What is the HIV prevalence rate among pregnant women tested at PMTCT sites in the past year?</td>
<td>2. What is the HIV prevalence rate among PMTCT clients?</td>
</tr>
<tr>
<td>3. For this level of the logistic system, what was the beginning inventory for each brand of test at the start of the year?</td>
<td>3. What percentage of pregnant women in the catchment area will make at least one ANC visit?</td>
<td>3. What is the average discordance rate between the screening and confirmatory tests?</td>
<td>3. What is the average discordance rate between the screening and confirmatory tests?</td>
</tr>
<tr>
<td>4. For this level of the logistic system, what were the receipts for each brand of test for the year?</td>
<td>4. What percentage of these ANC clients is likely to request counseling for HIV?</td>
<td>4. What is the expected rate of change for PMTCT testing?</td>
<td>4. What is the testing protocol for PMTCT?</td>
</tr>
<tr>
<td>5. For this level of the logistic system, what were the expiries, losses, and adjustments for each brand of test for the year?</td>
<td>5. What percentage of ANC clients counseled is likely to request an HIV test?</td>
<td>5. What is the testing protocol for PMTCT?</td>
<td></td>
</tr>
<tr>
<td>6. For this level of the logistic system, what was the ending inventory for each brand of test for the year?</td>
<td>6. What is the HIV prevalence rate among PMTCT clients?</td>
<td>6. What is the testing protocol for PMTCT?</td>
<td></td>
</tr>
<tr>
<td>7. What is the expected rate of change of HIV test consumption for PMTCT?</td>
<td>7. What is the average discordance rate between the screening and confirmatory tests?</td>
<td>7. What is the testing protocol for PMTCT?</td>
<td></td>
</tr>
</tbody>
</table>

**Quality Control and Wastage Factors**

1. What percentage of each brand of test will be used for quality control purposes?
2. What percentage of each brand of test will be wasted through expiry, faulty product, etc.?

**Service Capacity**

1. For the PMTCT program, what is the total number of counselors?
2. How many days a year, on average, will a counselor do PMTCT?
3. Do counselors themselves conduct HIV tests? **YES ☐ NO ☐**
4. If YES, proceed to question #4A. If NO, proceed to question #4B.

(Continue with question 4A or 4B on the next page)
4A. On average, how many PMTCT clients per day will a counselor counsel if this same counselor is also conducting the tests?

5A. What percentage of counseled clients is likely to request HIV testing?

6A. If reliable service capacity data is not available, discuss with key informants the counseling and testing capacity for PMTCT. Using this information, determine the maximum number of clients who can be tested in the program for the testing of HIV-exposed babies during the year you are quantifying.

4B. On average, how many PMTCT clients per day will a counselor counsel?

5B. What percentage of counseled clients is likely to request HIV testing?

6B. For the PMTCT program, what is the total number of technicians conducting HIV tests?

7B. How many days a year, on average, will a technician conduct HIV tests for PMTCT?

8B. On average, how many HIV tests for PMTCT will a technician conduct per day?

9B. If reliable service capacity data is not available, discuss with key informants the testing capacity for PMTCT. Using this information, determine the maximum number of clients who can be tested in the program for the testing of HIV-exposed babies during the year you are quantifying.

If an ELISA/Blot is picked for the test kit selection—

10B. What is the yearly laboratory machine capacity for conducting the HIV test indicated in the product selection for PMTCT?
### DEMAND

<table>
<thead>
<tr>
<th>Logistics</th>
<th>Demographic/ Morbidity</th>
<th>Service Statistics</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How many of each brand of tests were consumed during the past year for testing HIV-exposed babies?</td>
<td>1. What percentage of babies of HIV-positive PMTCT clients will be brought for HIV testing at age 9 months?</td>
<td>1. How many HIV-exposed babies were tested in the ANC sites offering PMTCT during the previous year?</td>
<td></td>
</tr>
<tr>
<td>2. What is the lowest level of the system having relatively complete data?</td>
<td>2. What is the percentage of HIV-exposed babies who test HIV-negative at age 9 months?</td>
<td>2. What was the HIV prevalence rate among HIV-exposed babies tested at ANC clinics?</td>
<td></td>
</tr>
<tr>
<td>3. For this level of the logistic system, what was the beginning inventory for each brand of test at the start of the year?</td>
<td>3. What percentage of HIV-negative babies at age 9 months will still be breastfeeding?</td>
<td>3. What is the average discordance rate between the screening and confirmatory tests?</td>
<td></td>
</tr>
<tr>
<td>4. For this level of the logistic system, what were the receipts for each brand of test for the year?</td>
<td>4. What percentage of HIV-negative babies at age 9 months will still be breastfeeding at 9 months will be brought for retesting 3 months after being weaned from breast milk?</td>
<td>4. What is the expected rate of change for testing HIV-exposed babies?</td>
<td></td>
</tr>
<tr>
<td>5. For this level of the logistic system, what were the expiries, losses, and adjustments for each brand of test for the year?</td>
<td>5. What percentage of HIV-negative babies still breastfeeding at 9 months will be brought for retesting at age 18 months?</td>
<td>5. What is the testing protocol for testing HIV-exposed babies?</td>
<td></td>
</tr>
<tr>
<td>6. For this level of the logistic system, what was the ending inventory for each brand of test for the year?</td>
<td>6. What percentage of HIV-positive babies at age 9 months will be brought for retesting at age 18 months?</td>
<td>6. What is the testing protocol for testing HIV-exposed babies to be tested in the year you are quantifying?</td>
<td></td>
</tr>
<tr>
<td>7. What is the expected rate of change of HIV test consumption for testing HIV-exposed babies?</td>
<td>7. What percentage of HIV-positive babies at age 18 months will still be breastfeeding?</td>
<td>7. What is the HIV prevalence rate among HIV-exposed babies?</td>
<td></td>
</tr>
<tr>
<td>8. What percentage of HIV-negative babies still breastfeeding at 18 months will be brought for retesting 3 months after being weaned from breast milk?</td>
<td>9. What is the average discordance rate between the screening and confirmatory tests?</td>
<td>8. What is the average discordance rate between the screening and confirmatory tests?</td>
<td></td>
</tr>
<tr>
<td>9. What is the testing protocol for testing HIV-exposed babies?</td>
<td>10. What is the expected rate of change for testing HIV-exposed babies?</td>
<td>9. What is the testing protocol for testing HIV-exposed babies?</td>
<td></td>
</tr>
</tbody>
</table>

---

**APPENDIX C** 51
Quality Control and Wastage Factors

1. What percentage of each brand of test will be used for quality control purposes?
2. What percentage of each brand of test will be wasted through expiry, faulty product, etc.?

Service Capacity

1. In the program for testing of HIV-exposed babies, what is the total number of counselors?
2. How many days a year, on average, will a counselor counsel caregivers of HIV-exposed babies?
3. Do counselors conduct HIV tests? YES ☐ NO ☐
   If YES, proceed to question #4A. If NO, proceed to question #4B.

4A. On average, how many caregivers of HIV-exposed babies will a counselor counsel per day if this same counselor is also conducting the tests?

5A. If reliable service capacity data are not available, discuss with key informants the counseling and testing capacity for testing HIV-exposed babies. Using this information, determine the maximum number of clients who can be tested in the PMTCT program during the year you are quantifying.

4B. On average, how many caregivers of HIV-exposed babies will a counselor counsel per day if the counselors are not conducting the tests?

5B. For the testing of HIV-exposed babies program, what is the total number of technicians conducting HIV tests?

6B. How many days a year, on average, will a technician conduct HIV tests for the testing of HIV-exposed babies program?

7B. On average, how many HIV tests for the testing of HIV-exposed babies will a technician conduct per day?

8B. If reliable service capacity data are not available, discuss with key informants the testing capacity for the testing of HIV-exposed babies program. Using this information, determine the maximum number of clients who can be tested in the PMTCT program during the year you are quantifying.

If an ELISA/Blot is picked for the test kit selection—

9B. What is the yearly laboratory machine capacity for conducting the HIV test indicated in the product selection for the testing of HIV-exposed babies program?
### TABLE 5. DATA REQUIRED TO FORECAST ADJUSTED DEMAND FOR HIV TESTS FOR SENTINEL SURVEILLANCE

<table>
<thead>
<tr>
<th>Logistics</th>
<th>Demographic/Morbidity</th>
<th>Service Statistics</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>1. How many people will be tested for HIV in the sentinel surveillance program in the year you are quantifying?</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2. How many or what percentage of the screened specimens will be tested for quality control?</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3. What is the average discordance rate between the screening and quality control tests, or what percentage or number of the quality control tests will require validation testing?</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4. What is the testing protocol for sentinel surveillance?</td>
</tr>
</tbody>
</table>

**Quality Control and Wastage Factors**

1. What percentage of each brand of test will be used for quality control purposes?
2. What percentage of each brand of test will be wasted through expiry, faulty product, etc.?

**Service Capacity**

1. For sentinel surveillance, what is the total number of technicians conducting HIV tests?
2. How many days a year, on average, will a technician conduct HIV tests for sentinel surveillance?
3. On average, how many HIV tests for sentinel surveillance will a technician conduct per day?
   - OR -
4. If reliable service capacity data is not available, discuss with key informants the testing capacity for sentinel surveillance. Using this information, determine the maximum number of tests that can be conducted for sentinel surveillance during the year you are quantifying.
   
   If an ELISA/Blot is picked for the test kit selection—
5. What is the yearly laboratory machine capacity for conducting the HIV test indicated in the product selection?
<table>
<thead>
<tr>
<th>Logistics</th>
<th>Demographic/ Morbidity</th>
<th>Service Statistics</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How many of each brand of tests were consumed in the past year for HCT?</td>
<td>1. What is the population of the catchment areas of health facilities receiving HIV tests under this program?</td>
<td>1. How many HIV tests were conducted in clinical settings during the past year for diagnostic testing?</td>
<td>1. What is the anticipated number of clients to be tested for HIV through HCT in the year you are quantifying?</td>
</tr>
<tr>
<td>2. What is the lowest level of the system having relatively complete data?</td>
<td>2. What percentage of the population in the catchment area will access medical facilities this year?</td>
<td>2. What is the expected rate of change in HIV testing through HCT in the year you are quantifying?</td>
<td>2. What is the HIV prevalence rate of clients tested for HIV through HCT?</td>
</tr>
<tr>
<td>3. For this level of the logistic system, what was the beginning inventory for each brand of test at the start of the year?</td>
<td>3. What percentage of individuals accessing medical facilities is tested for HIV?</td>
<td>3. How many of the HIV tests conducted in the past year through HCT testing were HIV-positive?</td>
<td>3. What is the average discordance rate between the screening and confirmatory tests?</td>
</tr>
<tr>
<td>4. For this level of the logistic system, what were the receipts for each brand of test for the year?</td>
<td>4. In the catchment areas, what is the AIDS prevalence of the population accessing medical facilities?</td>
<td>4. What is the average discordance rate between the screening and confirmatory tests?</td>
<td>4. What is the testing protocol for HCT?</td>
</tr>
<tr>
<td>5. For this level of the logistic system, what were the expiries, losses, and adjustments for each brand of test for the year?</td>
<td>5. What is the average discordance rate between the screening and confirmatory tests?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. For this level of the logistic system, what was the ending inventory for each brand of test for the year?</td>
<td>6. What is the testing protocol for HCT?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. What is the expected rate of change of HIV test consumption for HCT?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Quality Control and Wastage Factors**

1. What percentage of each brand of test will be used for quality control purposes?
2. What percentage of each brand of test will be wasted through expiry, faulty product, etc.?

**Service Capacity**

1. For HCT, what is the total number of technicians conducting HIV tests?
2. How many days a year, on average, will a technician conduct HIV tests for HCT?
3. On average, how many HIV tests for HCT will a technician conduct per day?

   -- OR --

4. If reliable service capacity data is not available, discuss with key informants the testing capacity for HCT. Using this information, determine the maximum number of tests that can be conducted for HCT during the year you are quantifying.

If an ELISA/Blot is picked for the test kit selection—

5. What is the yearly laboratory machine capacity for conducting the HIV test indicated in the product selection?
### TABLE 7. DATA REQUIRED TO FORECAST ADJUSTED DEMAND FOR HIV TESTS FOR OTHER USES (INCLUDING TRAINING AND RESEARCH)

<table>
<thead>
<tr>
<th>Logistics</th>
<th>Demographic/Morbidity</th>
<th>Service Statistics</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How many of each brand of tests were consumed during the past year² for the other uses you are quantifying?</td>
<td></td>
<td>1. How many clients were tested for HIV in the past year² for the other uses you are quantifying?</td>
<td>1. How many clients are targeted to be tested for HIV for the other use(s) you are quantifying?</td>
</tr>
<tr>
<td>2. What is the lowest level of the system having relatively complete data?</td>
<td></td>
<td>2. What is the percentage expected rate of change in testing for the other uses you are quantifying?</td>
<td>2. What is the HIV prevalence rate for clients tested for the other use(s) you are quantifying?</td>
</tr>
<tr>
<td>3. For this level of the logistic system, what was the beginning inventory for each brand of test at the start of the year?</td>
<td>N/A</td>
<td>3. What is the HIV prevalence rate for clients tested for the other uses you are quantifying?</td>
<td>3. What is the average discordance rate between the screening and confirmatory tests?</td>
</tr>
<tr>
<td>4. For this level of the logistic system, what were the receipts for each brand of test for the year?</td>
<td></td>
<td>4. What is the average discordance rate between the screening and confirmatory tests?</td>
<td>4. What is the testing protocol for the other use(s) you are quantifying?</td>
</tr>
<tr>
<td>5. For this level of the logistic system, what were the losses and adjustments for each brand of test for the year?</td>
<td></td>
<td>5. What is the testing protocol for the other use(s) you are quantifying?</td>
<td></td>
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<tr>
<td>6. For this level of the logistic system, what was the ending inventory for each brand of test for the year?</td>
<td></td>
<td></td>
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<tr>
<td>7. What is the expected rate of change of HIV test consumption for other uses?</td>
<td></td>
<td></td>
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### Quality Control and Wastage Factors

1. What percentage of each brand of test will be used for quality control purposes?
2. What percentage of each brand of test will be wasted through expiry, faulty product, etc.?
Service Capacity

1. For the other use(s) you are quantifying, what is the total number of technicians conducting HIV tests?
2. How many days a year, on average, will a technician conduct HIV tests for the other use(s) you are quantifying?
3. On average, how many HIV tests for the other use(s) you are quantifying will a technician conduct per day?
   – OR –
4. If reliable service capacity data are not available, discuss with key informants the testing capacity for the other uses you are quantifying. Using this information, determine the maximum number of tests that can be conducted for the uses during the year you are quantifying.
   If an ELISA/Blot is picked for the test kit selection—
5. What is the yearly laboratory machine capacity for conducting the HIV test indicated in the product selection?
DELIVER
DELIVER, a six-year worldwide technical assistance support contract, is funded by the President’s Emergency Plan for AIDS Relief (PEPFAR) through the U.S. Agency for International Development (USAID).

Implemented by John Snow, Inc. (JSI), (contract no. HRN-C-00-00-00010-00) and subcontractors (Manoff Group, Program for Appropriate Technology in Health [PATH], and Social Sectors Development Strategies, Inc.), DELIVER strengthens the supply chains of health and family planning programs in developing countries to ensure the availability of critical health products for customers. DELIVER also provides technical management of USAID’s central contraceptive management information system.

Recommended Citation

Abstract
The global scale up of ART programs in resource-limited settings, and the increase of U.S. government support in this effort, has increased global funding levels and the demand for HIV/AIDS commodities. To meet this demand, the USAID-funded DELIVER project has taken on a role in procuring these commodities using USG funds. This paper outlines key lessons and insights from DELIVER's two-plus years of experience in procuring HIV/AIDS commodities using USG Funds.
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<tr>
<th>ACRONYM</th>
<th>FULL FORM</th>
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<tbody>
<tr>
<td>AAPD</td>
<td>Acquisition and Assistance Policy Directive</td>
</tr>
<tr>
<td>AIDAR</td>
<td>Agency for International Development Acquisition Regulations</td>
</tr>
<tr>
<td>AIDS</td>
<td>acquired immune deficiency syndrome</td>
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<td>ARV</td>
<td>antiretroviral</td>
</tr>
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<td>CA</td>
<td>Crown Agents</td>
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<tr>
<td>CDC</td>
<td>Centers for Disease Control</td>
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<td>CHAZ</td>
<td>Chrchues Association of Zambia</td>
</tr>
<tr>
<td>CIDRZ</td>
<td>Center for Infectious Disease Research in Zambia</td>
</tr>
<tr>
<td>CRS</td>
<td>Catholic Relief Services</td>
</tr>
<tr>
<td>CTO</td>
<td>Cognizant technical officer</td>
</tr>
<tr>
<td>FAR</td>
<td>Federal Acquisition Regulation</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
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<tr>
<td>GMP</td>
<td>Good manufacturing practice</td>
</tr>
<tr>
<td>GRZ</td>
<td>Government of Zambia</td>
</tr>
<tr>
<td>HHS</td>
<td>United States Department of Health and Human Services</td>
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<tr>
<td>HIV</td>
<td>human immunodeficiency virus</td>
</tr>
<tr>
<td>INCOTERM</td>
<td>International Commercial Terms</td>
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<td>JICA</td>
<td>Japan International Cooperation Agency</td>
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<td>JSI</td>
<td>John Snow Inc.</td>
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<tr>
<td>MOH</td>
<td>Ministry of Health</td>
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<tr>
<td>MSH</td>
<td>Management Sciences for Health</td>
</tr>
<tr>
<td>NGO</td>
<td>Non-governmental organization</td>
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<tr>
<td>OAA</td>
<td>Office of Acquisition and Assistance</td>
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<tr>
<td>PSCMS</td>
<td>Partnership for Supply Chain Management System</td>
</tr>
<tr>
<td>RFTOP</td>
<td>Request for task order proposal</td>
</tr>
<tr>
<td>RPM</td>
<td>Rational Pharmaceutical Management</td>
</tr>
<tr>
<td>PEPFAR</td>
<td>President’s Emergency Plan for HIV/AIDS Relief</td>
</tr>
<tr>
<td>UNICEF</td>
<td>United Nations International Children's Emergency Fund</td>
</tr>
<tr>
<td>USAID</td>
<td>United States Agency for International Development</td>
</tr>
<tr>
<td>USG</td>
<td>United States Government</td>
</tr>
<tr>
<td>TBA</td>
<td>traditional birth attendant</td>
</tr>
<tr>
<td>TFGI</td>
<td>The Futures Group International</td>
</tr>
<tr>
<td>TFR</td>
<td>total fertility rate</td>
</tr>
<tr>
<td>UNFPA</td>
<td>United Nations Population Fund</td>
</tr>
<tr>
<td>USAID</td>
<td>United States Agency for International Development</td>
</tr>
<tr>
<td>WRA</td>
<td>women of reproductive age</td>
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</table>
ACKNOWLEDGMENTS

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INTRODUCTION

The procurement of HIV/AIDS commodities is a complicated process that varies according to the source of funding for procurement, the recipients, and the recipient country regulations that are in place. The global scale-up of HIV/AIDS treatment and care has increased the availability and accessibility of those services, as well as the commodities required to provide the services. In many countries, the scale-up has also increased the complexity of the procurement environment and process because it has increased the number of players and steps involved in procurement.

Procurement procedures for HIV/AIDS commodities vary from donor to donor and from country to country. A number of the major players in this arena (e.g., the World Bank, the Global Fund, the United Nations International Children's Emergency Fund [UNICEF], and others) have published detailed guidelines for procuring HIV/AIDS commodities when using their funds or their procurement mechanisms. Those guidelines are extremely useful resources for countries that have set priorities for expansion of HIV/AIDS programs and services, and that may be recipients of some or all of the funding streams. Countries generally dedicate a portion of donated funds to procure commodities that will support program expansion, so having access to clear, user-friendly guidelines that will help countries understand and follow complex procedures will enable programs to procure quality products in a timely manner.

The U.S. government (USG) is a relatively recent player in the arena of global procurement of HIV/AIDS commodities. Nonetheless, since the launch of the President's Emergency Plan for AIDS Relief Program (PEPFAR) in 2003—with its US$15 billion commitment to HIV/AIDS prevention, care, and treatment activities—USG has become a key provider of HIV/AIDS commodities for programs in resource-poor countries. Just as the World Bank and the United Nations Population Fund have their own guidelines for procurement, the USG also has a set of regulations that must be followed when procuring HIV/AIDS commodities using USG funds. Thus, organizations that procure commodities using USG funds must understand the technical and program requirements, as well as the rules and regulations that must be followed for the process. If organizations are to successfully complete the procurement, multiple steps must be taken, often simultaneously, by various stakeholders involved in the process.

The DELIVER project, implemented by John Snow, Inc. (JSI), has been involved in procuring HIV/AIDS commodities using USG funds since 2003. Over the two-and-a-half year period, the processes have evolved, and the project has gained experience and expertise in this specialized area. This guide aims to provide contextual insights and qualitative lessons that have been learned in procuring HIV/AIDS commodities while using USG funds. The guide was specifically developed as a resource to support USAID Missions, cooperating agencies, and other organizations and agencies that receive USG funds so they can obtain HIV/AIDS commodities. The lessons will be particularly relevant to organizations for which procurement is not a core activity and that may decide to outsource certain procurement functions to a procurement agent.

This guide is by no means an exhaustive reference to procurement of HIV/AIDS commodities using USG funds. Several useful resources exist that document both general procurement guidelines and specific USG/USAID procurement guidelines. Those documents are included in the reference list at the end of this work. The intention of the guide is to offer unique insights into the process on the basis of the contextual information and lessons learned from DELIVER's experience, which may not be available in other published guides.
The guide begins with a basic overview of USG procurement rules and regulations and the procurement mechanisms available to organizations. It then provides the specific lessons learned from DELIVER’s more than two years of experience in procuring HIV/AIDS commodities using USG funds. It also includes the step-by-step approach that DELIVER has used.
SUMMARY OF USG PROCUREMENT RULES AND REGULATIONS CONCERNING HIV/AIDS COMMODITIES

Organizations using USG funds to purchase HIV/AIDS commodities must abide by the U.S. government’s procurement rules and regulations. Those regulations are intended to ensure a minimum level of product quality and assurance to both the client and the U.S. taxpayers that the money is being used to obtain quality, efficacious products in a transparent manner.

Many organizations must also follow their specific contractual obligations, in addition to federal and USAID procurement regulations. For example, the DELIVER project is bound by contractual requirements between JSI and its funder, USAID. Therefore, when procuring commodities through the DELIVER project, JSI must adhere to its contractual obligations in order to use USG funds appropriately. Contracts vary from organization to organization; thus, each organization must be sure to review its own terms and guidelines and its incorporated regulations to ensure compliance.

In summary, while reliant on USG rules and regulations and on specific contractual requirements, a project must consider the need for the following three types of waivers or approvals when procuring HIV/AIDS commodities using USG funds:

- Does the organization require “Approval to Purchase Restricted Commodities?”
- For each commodity, is a “Source and Origin Waiver” required?
- Is approval necessary to purchase commodities over an authorized threshold, as indicated in the organization’s contract?

RESTRICTED COMMODITIES PURCHASE APPROVAL
Pharmaceutical products, including HIV/AIDS commodities such as drugs and test kits, are classified as “restricted commodities” under the USAID procurement regulations (as defined in the Automated Directives System and the Code of Federal Regulations). Under USG regulations—until the time that a blanket waiver exists for all restricted commodities—organizations that plan to procure restricted commodities must request approval from OAA.

SOURCE AND ORIGIN WAIVER
In addition, all pharmaceutical products procured with USG funds must be deemed safe and of a certain standard of quality. In most cases, this requirement means that the products must be approved by the U.S. Food and Drug Administration (FDA). Preference is also given to commodities whose source and origin is the United States. In special circumstances, approvals may be sought to purchase non-FDA approved commodities whose source, origin, or both is outside the United States.
APPROVAL TO PURCHASE COMMODITIES OVER AN AUTHORIZED THRESHOLD

Organizations must review their own contract to determine whether they require approval to purchase commodities over an authorized threshold. For example, The DELIVER contract has a restriction under Federal Acquisitions Regulation (FAR) 52.244-2, which requires approval from the Office of Acquisition and Assistance (OAA) within USAID for any procurement of goods that exceed US$100,000 in value. Therefore, in addition to requesting approval to procure restricted commodities, DELIVER’s contract requires that the project seek approval to procure goods that exceed US$100,000 in value.
The process of actually procuring HIV/AIDS commodities can occur through a number of different mechanisms. Organizations may elect to do the following:

- Procure the commodities themselves by negotiating all contracts for the goods directly with the manufacturers and by monitoring all shipments and payments.

- Use the expertise of a procurement services agency that is experienced in HIV/AIDS commodity procurement to assist with contract negotiation and shipment monitoring. Hiring a procurement agent, however, does not preclude an organization from meeting its own responsibilities to monitor contracts, shipments, and payments.

- Use a hybrid method of procurement by outsourcing selected components of the procurement process. For example, an organization may elect to use the expertise of multiple partners, such as a combination of procurement agents, organizations, or both (DELIVER, the Partnership for Supply Chain Management or Management Sciences for Health/Rational Pharmaceuticals Management Plus) that have specific expertise in different aspects of procurement.

DELIVER elected to use its team subcontractor, Crown Agents, as its agent in the procurement of HIV/AIDS commodities. Although the general lessons and process for procurement are applicable to other agencies procuring HIV/AIDS commodities, some steps are specific to DELIVER's relationship with Crown Agents, as well as to its contractual obligations with its funder, USAID.
LESSONS LEARNED FROM DELIVER

BACKGROUND
Although the DELIVER contract does not grant JSI approval to procure restricted commodities, over the past two and a half years, DELIVER has been approached by a number of USAID Missions to procure HIV/AIDS commodities with its available USG funds. To meet the Missions’ requests—which, in turn, was to assist countries to meet program targets—the DELIVER project had to comply with a process of requesting waivers and approvals to purchase restricted commodities and to procure commodities at levels exceeding US$100,000.

DELIVER’s efforts in HIV/AIDS commodity procurement that is USG-funded began in 2003 in Zimbabwe and have since expanded to six countries in conjunction with the growth of the President’s Emergency Plan for AIDS Relief (PEPFAR) program. Following is the list of countries where the project has handled the procurement of PEPFAR-funded supplies:

- Angola (HIV test kits)
- Kenya (HIV test kits and laboratory reagents and supplies)
- Mozambique (ARVs)
- Tanzania (ARVs)
- Zambia (ARVs and HIV test kits)
- Zimbabwe (ARVs and HIV test kits)

DELIVER initially documented its experience and lessons from procuring commodities in the first few countries where procurements were completed, to guide the process in other countries. Over time, the lessons have been refined and can be shared more broadly to provide insights to organizations contemplating this process for the first time or to help refine existing processes for organizations already procuring the commodities.

LESSONS LEARNED FROM SIX COUNTRIES: EXPECT THE UNEXPECTED
One of the overall lessons learned is that, regardless how well organized, planned, or managed partners are in the procurement process, unexpected delays are unavoidable. The following lessons were found to be helpful in minimizing the negative impact on product availability and program goals of unexpected delays, and in enabling DELIVER and its partners to respond in a flexible and agile way to challenges encountered throughout the process. DELIVER’s experience has been categorized in the following 10 lessons.
The first lesson is that each recipient country has unique requirements and regulations. Start the procurement and pre-procurement process early so that unexpected delays in procurement and importation of commodities do not undermine program goals.

Although general steps in the procurement process may be learned, understood, and improved over time, each country’s procurement process and players are unique. Mozambique, which started procuring commodities in late 2005, was able to learn from the procurement processes and challenges faced in other countries, but the country’s unique importation processes and requirements were the main causes of obstacles and delays.

Another potential cause of unexpected delay can occur during a preprocurement step such as quantification. Generally, requests for DELIVER to procure commodities are associated with availability of funds and, therefore, are usually not preceded by completed estimation of needs. In such situations, the first step is to conduct national or program quantifications, which can be a lengthy process depending on the program’s readiness. As an example, if a program’s standard treatment guidelines or testing algorithms are in flux or are not finalized, they must be completed before quantifying needs.

The process of finalizing standardizing treatment and testing guidelines can take several months and can create significant delays in product availability. Programs that have complete and updated quantifications can engage in procurement planning as soon as funds are available for procurement. After the quantification is complete, the required date for the arrival of the commodities in-country is established. That date is fixed even before the procurement process commences, which helps to establish a clear idea and timeline throughout the procurement process for when the product is required in-country.

The second lesson is that many HIV/AIDS programs are new or rapidly expanding, thereby making forecasts less reliable than for stable programs. Build flexibility into the procurement plan and into the shipment schedule to minimize product wastage and to ensure that manufacturers can continue to meet global demand.

Organizations that can influence procurement planning should build in flexible mechanisms such as smaller, more frequent shipments for products for new programs (e.g., ARV drugs and HIV tests). Although this step might be slightly more costly in the short term, there are likely to be long-term savings if uptake in ARV drug consumption, for example, is not as high as forecasted and if products begin to pile up in-country. Planning for smaller, more-frequent shipments enables programs to avoid bringing in more commodities when programs are overstocked. Conversely, if product uptake is much higher than expected, such as increasing needs for HIV test kits by a given program, quantities can be added to existing, planned shipments to prevent additional, costly emergency shipments.

However, it is important to keep in mind as programs expand that phasing procurement across several suppliers can add up to several shipments. Because suppliers may not always strictly adhere to delivery dates, programs might receive a number of partial shipments, in addition to those shipments already planned. The importance of regular monitoring and of clear and consistent updates by the procurement agent are critical components for enabling programs to stay on track and to navigate the confusion generated by multiple shipments.

It is important to monitor HIV/AIDS commodity consumption in programs on a regular basis and to ensure that updates are reflected in procurement plans. With ARVs for example, slow uptake, especially for second-line drugs, has led to changes within procurement orders, thus resulting in fewer drugs arriving in-country, and has resulted in significant cost savings for in-country programs. Those funds can be and have been reallocated for different HIV/AIDS procurement needs or for HIV/AIDS-related program activities.
Effective coordination of all partners involved in procurement or in supply chain management of HIV/AIDS commodities in a country is time-consuming but can result in significant benefits for the program and for all partners involved. Many programs receive funding for HIV/AIDS commodities from multiple sources, and procurement is often conducted through various mechanisms, all of which have different lead times. Convening a single forum for regularly sharing information on quantities of commodities being procured and on timeframes for receipt among all partners involved in procuring, financing, and quantifying HIV/AIDS commodities can facilitate problem solving when delays are experienced. In many cases, different partners may bring in the same or similar commodities. Delays in the receipt of one shipment could be compensated for by temporary loans from other available stocks—if such information is shared with enough time to prevent stockouts.

Furthermore, coordinating information among all partners builds a sense of shared ownership of the quantities to procure and a sense of shared responsibility for resolving stock shortages or imbalances that arise for various reasons, including delays in procurement. It is often the case in new and expanding programs that actual consumption may not come close to forecasted projections. When commodities are in short supply, or when they are overstocked and likely to expire, resolving those issues in partner forums is likely to be effective for finding solutions.

A snapshot of the procurement situation in Zambia provides a useful example of why coordination is critical and of how coordination can be important for addressing commodity imbalances. There are four sources for HIV test kit procurement and five sources for procuring ARVs. The landscape of procurement agencies and organizations is more complicated, with multiple agencies procuring for each funding stream.

Five agencies are involved in HIV test kit procurement:

- Japan International Cooperation Agency conducts direct procurement using its own funds.
- UNICEF procures HIV test kits on behalf of GRZ while using funds from the Global Fund.
- The Centers for Disease Control procures HIV test kits using PEPFAR funds.
- DELIVER and Crown Agents procure HIV test kits using USG funds.

Five agencies are involved in procurement of ARV drugs:

- GRZ procures ARV drugs using Global Fund monies and its own funds.
- UNICEF procures ARV drugs using Global Fund monies received by GRZ.
- DELIVER and Crown Agents procure ARV drugs using PEPFAR funds.
- Catholic Relief Services (CRS) procures ARV drugs for the Christian Health Association of Zambia using PEPFAR funds.
- The Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) procures ARV drugs for its Zambian partner, CIDRZ, using PEPFAR funds.
All implementing partners involved in ARV drug procurement agreed to, and participated in, a national forecast for ARVs. That forecast provided the basis for discussions with the various funding sources to ensure that there was sufficient funding to cover forecast needs. The implementing partners also regularly make available information on their issues to facilities, their stock on hand, and their planned shipments. That information provides a picture of the national stock situation. Implementing partners have begun using JSI’s procurement planning software—PipeLine—to facilitate the timely sharing of key information, including the number of months of supply by product. By sharing data, the partners have been able to take concrete actions to maximize product availability.

As an example, one partner had 50 months of supply of Efavirenz 50mg, almost guaranteeing expiration and waste, while another was stocked out. The partners were able to transfer stock, allowing the stocked-out partner to meet demand for Efavirenz 50mg and to cancel future shipments until the stock in-country was used, thereby lessening the chance of expiration and maximizing the use of valuable resources. Similarly, when all PEPFAR partners were experiencing delays in the availability of Combivir because of global shortages by the manufacturer, sharing information allowed them to transfer stocks to avoid stockouts in the various programs and to update one another on mechanisms for fast-tracking procurement of other sources of approved AZT/3TC.

The fourth lesson is that developing and maintaining procedures for regular and clear communication among all partners involved in the procurement process can help clarify roles and can reduce delays related to lack of understanding of complex steps and requirements. Designate a primary contact per organization or office to ensure clear and streamlined communication.

When outsourcing any or all components of the process to an organization or procurement agent, special attention must be paid to the execution of the agreement or to a scope of work. If an organization is to maximize progress and to ensure that all steps in the process are followed—so there will be timely product availability and adherence to federal, USG, and contractual obligations—detailed information must be collected, shared, used, and stored by many or all partners in the procurement process. This coordination can be done effectively only by the following:

• Establish clear procedures about regularity and mechanisms of communication. Not all partners need to be copied on all communication; information should be shared when appropriate and relevant. Nonetheless, the frequency of communication should be established for all partners, depending on their role.

• Designate individuals to serve as focal points for sharing information and for responding to queries within each organization or office, so that information exchange is not duplicative or contradictory.

• Design standard templates for collecting and sharing information.

• Ensure that all partners are regularly informed about issues that arise, including shipping changes, clearance delays, quality issues, payment requirements, and so on.

As an example of information sharing among implementing partners, both DELIVER and Crown Agents have individuals who have been designated to lead procurement-related activities from each organization. DELIVER has a senior commodity procurement advisor who is responsible for coordinating all procurement-related tasks between various implementing partners. Information is shared in a variety of ways:

• The senior commodity procurement advisor conducts weekly conference calls with the Crown Agents counterpart. During the calls, Crown Agents shares routine updates from the manufacturer, and DELIVER shares updates in quantities or in delivery dates from in-country field offices. Any outstanding issues or challenges are discussed or addressed during the calls.
Crown Agents also sends weekly updates on the status of ongoing procurements, in the form of a standard template that has been agreed on by the two organizations. The template was designed to reflect the tasks defined in the task order, so that progress based on deliverables could be clearly identified. Each country update is sent individually and is addressed to DELIVER’s procurement advisor, but relevant DELIVER country team staff members are copied on each email.

The procurement advisor sends monthly updates summarizing the status of procurement orders and funding across all countries to the project management and USAID/DC partners.

Queries from DELIVER field offices are directed to the procurement advisor, who can triage responses clearly and comprehensively.

All partners are copied on relevant issues that affect them. The list of partners includes DELIVER Washington, DELIVER staff in-country, Crown Agents, manufacturers, USAID/Washington, USAID Missions in-country, and agents contracted to clear and to forward products at the port of entry.

The fifth lesson is that establishing relationships with manufacturers by sharing commodity forecasts can minimize global commodity shortages and maximize product availability for recipient countries through strengthened relationships.

As part of its first procurement in Zimbabwe, DELIVER engaged in the negotiation of procurement terms and conditions with manufacturers for the first time. This process required a significant amount of time and resources. The situation was further exacerbated by an environment with numerous stakeholders and with specific procedures and regulations for the Accelerated Access Program, which covered differential pricing of ARVs and which complicated negotiations for issues related to shipping, customs, and payment terms.

Although initial relationships with manufacturers were slow to develop for DELIVER, regular contact has enhanced those relationships, and DELIVER is increasingly valued as a partner by manufacturers after sharing its forecasting data about commodities experiencing global shortages. Forecast information is valuable to manufacturers that are experiencing the strain of unpredictable, but increasing, global demand for ARV drugs and HIV test kits. Country and commodity specific forecasts enable manufacturers to prepare accurate production projections and, thus, to continue to expand their markets. Fewer global shortages and product availability crises also benefit recipient countries, donors, and organizations that are committed to ensuring continuous availability of HIV/AIDS products.

The sixth lesson is that maintaining detailed and up-to-date documentation can reduce delays in procurement and is necessary for fulfilling contractual obligations.

Proactively compiling and updating documents that are required for the procurement before they may be needed identifies gaps and missing information early in the process, which, in turn, reduces bottlenecks. Well-maintained records are necessary for providing precise information that is required to meet USG or recipient country regulations or for making decisions in the procurement process. Proactively compiling and updating documents become another key factor, in addition to establishing clear procedures that help partners navigate the process as efficiently as possible. Following are illustrative examples of documents that should be compiled early and updated regularly:

- A comprehensive list of ARV drugs, HIV test kits, and other commodities that are FDA-approved or are tentatively FDA-approved products, because USG funds cannot be used to purchase a commodity that does not fall into either category.

- For each recipient country, a comprehensive list of all ARV drugs (and other relevant drugs) registered for use in that country. It is important that this list include information on the manufacturer, on formulation, on
strength, and on packaging because changes in any of those factors may affect registration status. USG regulations determine that, if a product has the FDA’s tentative approval, it can be purchased only if it is registered for use in the recipient country. Thus, items on the procurement list that are “pending” registration may not be legally purchased using USG funds unless registration is fast-tracked or unless special waivers from the National Drug Regulatory Authority are obtained.

• A master list of details related to all previous procurements, including suppliers and prices, should be compiled as an easy reference. This master list is helpful in determining budgets and procurement plans for new countries, although details such as prices and shipping costs are likely to vary over time and by location, and will likely be specific to each country. This information, however, is still a useful starting point for initiating the process for a new country procurement.

• Copies of all relevant approvals, including OAA approvals, for the procurement files. This information is necessary to show adherence to contractual requirements in the case of an audit. Similar types of information may be needed, depending on each organization’s individual contracts. For example, when DELIVER began procuring restricted commodities, the blanket waiver for ARVs did not exist. Thus, the project had to obtain copies of GMP certificates for each manufacturing site from which the products had originated to demonstrate proof of FDA approvals in the case of an audit. The lack of a blanket waiver significantly complicated the procurement process for the project by introducing several additional steps that often caused delays.

The seventh lesson is that a blanket waiver can significantly reduce the complexity of the procurement process. When applying for a new blanket waiver or an amendment to blanket waivers, be sure to include an exhaustive list of commodities that the program is likely to purchase now and in the future.

The existing blanket waiver for ARV drugs was released in 2005 after DELIVER had some experience applying for source and origin waivers and approvals to purchase restricted commodities for procurements in Zimbabwe and Tanzania. The existence of the blanket waiver greatly reduced the number and the complexity of steps in the process. Once a product appears on the blanket waiver, neither the source and origin waiver nor the FDA approval for restricted commodity purchase is needed. Eliminating the source and origin waiver and the FDA-approval requirements can shorten the lead time by as much as two months. Unfortunately, the existing blanket waiver does not include all formulations, strengths, or manufacturing sites for all commodities purchased by DELIVER. Thus, organizations should be proactive about identifying all possible commodity formulations and strengths, as well as identifying manufacturing sites for future versions of the blanket waiver.

As an example, DELIVER set out to procure Tenofovir, 300 mg tablets, which is produced by Gilead Science, Inc., of Foster City, California. The tablets were listed on the blanket waiver of April 7, 2005, with an approved manufacturing facility of Patheon, Inc., in Mississauga, Ontario, Canada. Upon placing the order, DELIVER was informed that the product was no longer being manufactured and shipped from that facility but would be manufactured and shipped from the Altana Pharma Oranienburg GmbH facility in Oranienburg, Germany. In order to resolve this issue, DELIVER submitted the GMP certificate for the new facility as well as FDA approval documentation to USAID in order to apply for a source and origin waiver for the new facility.

The eighth lesson is to explore alternative mechanisms for ensuring that unregistered products can be legally imported into recipient countries. Limiting procured items to already registered products without exploring options could unnecessarily undermine program goals.

When USG funds are used to procure products, the items must be (tentatively) FDA-approved and registered for use in recipient countries. However, given the rapid changes in technology, which often result in the emergence of new drugs or new formulations or new strengths of existing drugs, a newly approved FDA product might not yet be registered for use in the recipient country. The onus of registration falls on the manufacturer. Given the
relatively high costs of registering and the sometimes lengthy processes once registration has started, manufacturers are sometimes reluctant to apply for registration status unless they know a market for the product exists. In some cases, the product might be the best alternative for the program because of its unique formulation or strength, for example, 600 mg capsules of Efavirenz (which reduces the pill burden for ART patients) or triple-fixed dose combinations (which can reduce pill burdens from six pills to two pills per day).

Before eliminating a product from options for procurement because of lack of registration, other alternatives for procurement should be explored. Those alternatives include mechanisms for fast-tracking registration and for receiving temporary authorization from the National Drug Regulatory Authority of a recipient country to import a nonregistered pharmaceutical. In Zimbabwe, the mechanism for obtaining temporary authorization is provided by “Section 75” of the National Drug policy, and was successfully used in the procurement of ARVs in 2004.

In Mozambique, where virtually no ARV drugs are registered, DELIVER was able to move forward with its procurements because the national director of health signed a letter stating that medicines, including ARV drugs destined for the public sector, do not need to be registered in-country.

In another scenario, the manufacturing plant for the (tentatively) FDA-approved product that is being purchased may not match the manufacturing plant for which registration was awarded in a given recipient country. As an example, Efavirenz purchased by DELIVER might originate from a manufacturing site in the Netherlands and, thus, allow DELIVER to meet USG regulations (because it is included on the blanket waiver), but the registration of Efavirenz in the recipient country might have been awarded for a manufacturing plant in a different country, for example, the United Kingdom. In such situations, although the chemical molecule (i.e., Efavirenz) is registered for use in the recipient country, the registration is specifically for a different production site. In Zimbabwe, this was the case for almost all drugs procured during 2004. USAID’s ADS guidelines enabled DELIVER to move forward with the manufacturing plants that the National Regulatory Drug Authority in the receiving country had registered, by considering that agency a “stringent regulatory authority.”

The ninth lesson is to develop a process map of the clearance process, to develop procedures, and to assign responsibilities at the country level for all steps in the process. Designating in-country responsibilities for monitoring shipments, payments, and clearance processes will reduce the lead time and lengthy delays, especially if communication procedures are well established.

Shipments can be delayed at numerous points in the process, and understanding the potential obstacles at each stage can help with preventive maintenance.

In Mozambique, DELIVER’s in-country staff is responsible for monitoring the progress of shipments through the following process:

- Deciding whether proforma invoices issued are in accordance with country requirements for importation
- Processing the importation license
- Issuing the import license to the supplier
- Determining whether a preshipment inspection was undertaken
- Learning whether authorization to ship has been issued by the country
- Communicating shipping details, and so on to customs clearance
- Knowing date of arrival at the airport and speed of customs clearance
- Establishing the timeframe for acceptance and entry into warehouse
Some obvious but critical pieces of information that can cause lengthy delays if they are unclear include the following: identifying the consignee information and sharing this information with suppliers, determining the length of the customs clearance process, and identifying regulations that govern acceptable remaining shelf lives on imported products.

It has been DELIVER’s experience that, despite the in-country’s staff undertaking primary responsibility for this monitoring, a critical factor in resolving bottlenecks has been to ensure that DELIVER’s procurement advisor is updated on all issues that occur throughout the process. Thus, when follow up with the procurement agent and manufacturers is required, it can be done instantly.

DELIVER’s in-country staff has also played critical roles in negotiating and monitoring contracts with local agents for clearing, storage, or distribution; for expediting customs clearance; and for acceptance of the product by the recipient. Negotiating and monitoring contracts at the country level has several benefits, including the ability of the staff member to customize the contract terms to the local environment. As an example, in Zimbabwe, DELIVER contracted with Geddes for customs clearance, storage, and distribution of ARVs to five USG-supported sites. Inflation is rampant in Zimbabwe, and a standard one- or two-year contract would have resulted in a severe devaluation of the contract price. A price ceiling was set to alleviate devaluation of the contract price, and purchase order contracts would be reissued quarterly to ensure that Geddes receives fair compensation for the work they perform.

The tenth lesson is that developing a step-by-step approach to HIV/AIDS commodity procurement can help multiple partners involved in procurement clearly understand and navigate the process, thereby reducing delays caused by miscommunication.

Organizations that are involved in procurement using USG funds should break down requirements into clearly defined steps with associated procedures to help all partners understand and navigate their individual roles. DELIVER has developed its own process, which is described in the following section. The steps are intended to help organizational staff members and procurement partners ensure a clear and consistent process for undertaking procurement of ARV drugs, HIV test kits, and laboratory supplies. The procurement process that is outlined below is identical for each type of commodity, unless stated otherwise. Although there may be some overlap between lessons presented previously and tasks that are outlined in the step-by-step approach, the stepwise process, in general, contains specific details about individual steps and timeframe that are not included in the lessons.
DELIVER’S STEP-BY-STEP PROCESS FOR PROCURING HIV/AIDS COMMODITIES USING USG FUNDS

As DELIVER gained experience in procurement, the project developed a step-by-step process that was standardized in all countries that met the dual objectives of implementing procurement in an efficient manner and according to the required regulations. The steps are presented in the order in which they should occur, but often two or more steps are carried out simultaneously.

Several of the steps are unique to DELIVER’s contractual requirements or to its approach of outsourcing selected procurement functions to its subcontractor, Crown Agents, and may not be relevant for all situations. Nonetheless, the steps illustrate the tasks that need to be accomplished along the way, and also provide insights into the required details and into where potential bottlenecks or delays may arise. A chart that visually depicts the sequencing of the steps is attached as appendix 1. The steps correspond to the following 12 categories:

Step 1  Obtain mission approval for procurement.
Step 2  Validate quantities to procure and develop a procurement plan with shipment schedule.
Step 3  Gather pre-task order information.
Step 4  Prepare and issue task order to the procurement agent.
Step 5  Confirm approval status for commodities.
Step 6  Prepare source and origin waiver (if commodities are not on blanket waiver).
Step 7  Obtain approvals from the Office of Acquisition and Assistance.
Step 8  Confirm in-country delivery process.
Step 9  Negotiate and issue contract to manufacturers.
Step 10  Place commodity orders.
Step 11  Monitor shipment and delivery process.
Step 12  Receive Commodities and Pay manufacturer.

The glossary of terms at the end of this guide defines the critical terms used in the steps and serves to clarify the use of those terms within this particular context. In addition, each step in the process may require the use of other references, listed at the end of this paper.
STEP 1. OBTAIN MISSION APPROVAL FOR PROCUREMENT.

The procurement of commodities requires written approval from the USAID Mission in-country. Programs must submit a written request to the Mission, seeking approval to procure the commodities. Before proceeding with the procurement, agencies should confirm that funds have been formally committed by the Mission for this procurement. After a formal written request is made to the Mission, the timeframe for the Mission to formally commit funding and to approve the procurement is between two and four weeks.

STEP 2. VALIDATE QUANTITIES TO PROCURE AND DEVELOP A PROCUREMENT PLAN WITH SHIPMENT SCHEDULE.

After Mission approval has been received, the procurement process can commence and should be based on a comprehensive list of commodities to be procured. This approval is usually obtained by reviewing or completing a quantification to determine the exact quantities of commodities to be procured. After the quantities to be procured have been determined and after a procurement plan and a shipment schedule have been developed, the quantities and plan should be validated by the recipient country’s Ministry of Health, the USAID Mission, and other relevant stakeholders. The procurement plan and shipment schedule should include proposed arrival date(s) in-country. This step should take approximately three to four weeks.

STEP 3. GATHER PRETASK ORDER INFORMATION.

A number of critical pieces of information, which are gathered at the beginning of the procurement process, will serve to inform the process and to assist in developing various documents that are necessary for the procurement (e.g., the task order for a procurement agent, negotiation of contracts with manufacturers). This information-gathering process typically takes between three and six months and can be an iterative process. Examples of useful information, documents to be compiled, or both are provided next:

• Ensure that commodities to be procured meet USG funding regulations and are FDA approved or tentatively FDA approved, by referencing the FDA’s Orange Book or the Health and Human Services’ Global health website.

• Investigate marking requirements for USAID donations by obtaining written guidance from the Mission. If there are sensitivities around implementing those requirements or if the costs are prohibitive, it is important to know that USAID Mission directors have the authority to waive any marking requirements. Although the AIDAR implies that the supplier shall ensure compliance with USAID marking, some manufacturers that DELIVER has worked with have refused to comply with the marking requirements for all of their products. JSI was successful in requesting and in receiving a waiver for all Global Health programs funded by the U.S. government, which waives marking requirements if they have an “adverse impact in the cooperating country.” (See AADP 05-11 of December 13, 2005.)

• Identify the following key information related to the in-country delivery process so as to minimize delays in this step:
  – The titleholder or the person or entity that the supplier will give the title of goods to after the consignment has been accepted. USAID or other host government entities (as approved in writing by USAID) must be the titleholder of the commodities.,
  – Consignee details, including the organization’s name, address, phone, fax, email, and ATTN: contact name and title must be present. The consignee may be a different entity from the titleholder and should ideally be USAID, a host government, or a hired warehouse or distributor. The consignee should be selected so that this entity handles the port clearance and in-country handling.
The point person in-country to receive the commodity invoices and DD 250 forms. Although this point person is generally the consignee, it is important to confirm that this assumption is true. The DD 250 document confirms that the consignment has arrived in-country, and it initiates the payment process for manufacturers.

Compile all relevant information from the quantification and procurement plan into the commodity procurement information table or a similar template. The table contains all information required for the procurement process and details exactly what type of product should be procured by specifying the product name, exact strength, dosage form, unit size, manufacturing site or plant, and country of manufacture.

It is important to keep in mind that there is a blanket waiver. In addition to identifying the commodities that have been approved for purchase, the waiver may also specify the manufacturing site for the product. Manufacturers, in fulfilling orders, may elect to source the product from a manufacturing site that is not listed on the blanket waiver, depending on the country location and product availability.

**STEP 4. PREPARE AND ISSUE TASK ORDER TO THE PROCUREMENT AGENT.**

This next step is relevant for organizations that outsource selected tasks to a procurement agent, and it involves preparing and issuing the task order to the agent. The time taken to process internal paperwork and contracts will vary from organization to organization, and the time depends on the complexity of the task order. Processing internal paperwork and contracts can sometimes be time-consuming, and that time should be factored into the planning process. It takes approximately two weeks for DELIVER to issue the task order to the procurement agent.

The primary purpose of this step is to use the commodity procurement information table and the procurement plan developed in previous steps to develop and negotiate a request for a task order proposal and a scope of work with the procurement agent. When preparing the scope of work for the procurement agent, as much detail as possible should be included, and tasks and deliverables should be clearly defined. Illustrative examples of important tasks and details include the following:

- Confirmation of in-country registration of all commodities
- Confirmation of the details of the commodity to be procured on the basis of the information contained in the commodity procurement information table
- Clarification of the process for sending DD 250 forms to in-country contacts for signature
- Description of the frequency and mode of progress reports and other communication updates from the procurement agent as part of the list of deliverables (e.g., weekly progress reports by email from the Crown Agents to the DELIVER procurement advisor)
- Determination of details related to contract negotiations with manufacturers, including clearly defining responsibilities of each party related to manufacturer contracts (e.g., Crown Agents’ responsibilities included negotiating the contract, reviewing information [type of commodity, quantity, packaging, components, etc.] for accuracy, reviewing delivery schedules, and confirming payment schedules)
- Confirmation of the shipping terms (incoterms), including establishing requirements for product shipping (e.g., door-to-door, door-to-port, etc.)
- Identification of the entity or entities to handle port clearance and customs clearance
The process for translating the scope of work into a finalized task order will also vary by organization. For DELIVER, the process includes using the complete scope of work to draft the request for task order proposal (RF TOP), which is sent to the procurement agent for review and for submission of feedback and budget. Once the RF TOP is approved and agreement has been reached between the organization and the procurement agent, the organization issues a task order to the procurement agent.

**STEP 5. CONFIRM APPROVAL STATUS FOR COMMODITIES.**

Step 5 involves using information supplied by the procurement agent (as part of the task order deliverables) to determine the next steps related to obtaining approvals and waivers. For DELIVER, most of this information is contained in the commodity procurement information table. The most important information to be confirmed for each commodity includes the following:

- **The FDA (tentative) approval status.** If the product is not FDA approved or tentatively FDA approved, USG funds cannot be used to purchase it until FDA or tentative FDA approval has been obtained.

- **The registration status in the recipient country.** If the commodity is not registered in-country, the organization’s country field office should highlight the issue to MOH, USAID, or other in-country counterparts, so the registration process can be fast-tracked or a temporary government exemption for the product to be imported can be obtained.

- **Inclusion of the commodity on the blanket waiver (if relevant) or documentation of GMP certificates for the manufacturing site.** The result of whether or not a commodity is included on the blanket waiver will result in different next steps for the organization. For the most part, either a change in formulation, in strength, or in manufacturing site might cause the commodity to be excluded from the provisions of the blanket waiver, which would then require the organization to undertake a more complex process for obtaining approvals and waivers. Thus, the organization should make an effort to negotiate necessary changes that would bring the list into compliance with the blanket waiver, if feasible. Some changes (e.g., drug strength) might be program requirements and, therefore, nonnegotiable. However, sourcing the product from a manufacturing site covered by the blanket waiver might be a feasible alternative that should be explored to reduce unnecessary and complicated steps in the procurement process.

On the basis of the result from the task in the third bullet above, one of three options must be followed:

- If the commodity is on the blanket waiver, then Step 6 is unnecessary and the tasks outlined in Step 7 (Obtain Approvals from the OAA) should be followed.

- If, however, the commodity is not on a blanket waiver, but if the organization has a GMP certificate on file, then the tasks outlined in Step 6 (Prepare a Source and Origin Waiver) need to be completed.

- If there is no GMP certificate on file for the commodity, then the organization must initiate the process of retrieving the GMPs either through the procurement agent, if one exists, or directly with the manufacturer. This process could take as long as two months. Once all relevant GMP certificates have been obtained, the organization should proceed to the next step, which is Step 6.
**REDUCING THE LEAD TIME FOR PROCUREMENT**

The following four steps, Steps 6–9, should all be undertaken simultaneously, to reduce the lead time for procurement.

Applying for all approvals at the same time will also streamline the process. Thus, the Source and Origin Waiver request should be submitted at the same time as the Approval to Purchase Restricted Commodities request and the Approval to Purchase Commodities over US$100,000 request. As mentioned previously, if commodities are procured using a blanket waiver, then an Approval to Purchase Restricted Commodities request is not necessary. However, an Approval to Purchase Commodities over the US$100,000 request must still be obtained.

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**STEP 6. PREPARE SOURCE AND ORIGIN WAIVER (IF COMMODITIES ARE NOT ON BLANKET WAIVER).**

For all commodities that are not on the blanket waiver, after a GMP certificate has been confirmed on file, a Source and Origin Waiver request must be submitted to USAID. The following documentation must be included in the blanket waiver request:

- Copy of country’s standard treatment guidelines
- Proof of FDA approval of drugs (FDA Orange Book)
- Proof of GMP certification for each manufacturing site for each drug
- Official letter from recipient country’s National Drug Regulatory Authority certifying the registration status of drugs
- A document permitting importation of nonregistered drugs.

Most organizations will use the preceding information to draft the action memorandum for the Source and Origin Waiver and the letter for submission to OAA. However, in the case of DELIVER, the draft action memorandum and the letter are prepared by the project to the contracting officer on behalf of the cognizant technical officer (CTO), who concurs with the request and then submits it to OAA for approval.

The submission and approval process takes between one and two months because of OAA’s schedule and timeframe for processing the request and for sending back the Source and Origin Waiver.

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**STEP 7. OBTAIN APPROVALS FROM THE OFFICE OF ACQUISITION AND ASSISTANCE.**

There are two types of approval that organizations may have to obtain from OAA as part of contractual requirements, in addition to the Source and Origin Waiver. Those approvals may not be necessary for other organizations. The process for obtaining the approvals consists of submitting a formal letter requesting the approvals from OAA, with relevant attachments, as described below. It is important to keep in mind that the approval to purchase commodities over US$100,000 can be combined with the restricted commodities approval, if both approvals are required. Receiving approval from OAA may take between one to two months.

- Approval to Purchase Restricted Commodities. The approval to purchase restricted commodities is never required if the commodity is on the blanket waiver, but the approval may or may not be required if a source and origin waiver is required. Determining the need for the approval to purchase restricted commodities depends
on the categorization of the commodity. Pharmaceutical products are restricted commodities and require this approval.

• Approval to Purchase Commodities over US$100,000. According to the terms of the DELIVER contract, if purchasing commodities for a value greater than US$100,000, USAID regulations require that the project first obtain approval from the OAA office before procuring any commodity or commodities totaling over US$100,000. The amount and approval process may differ among agencies, depending on their contractual obligations.

The package that is sent to OAA requesting those approvals should include the following information:

• The Commodity Procurement Information table, which lists the full name, exact strength, dosage form, manufacturing site, and country of manufacturer for each commodity
• An explanation, a justification, or both of why the commodity is required
• Written Mission approval
• The individual and total prices of commodities being procured
• A copy of a blanket waiver, a copy of the Source and Origin Waiver, or both

STEP 8. CONFIRM IN-COUNTRY DELIVERY PROCESS.

Before the organization or procurement agent places commodity orders—and if the procurement agent does not provide clearing and forwarding services—the organization or procurement agent should identify and contract with a clearinghouse or a clearing agent in-country and should discuss the logistics of the delivery process. All parties, including the organization, the procurement agent, the manufacturer, the in-country clearing agent, the country recipient organization, and the USAID should participate and agree on the steps and requirements in the delivery process. Refining the steps, responsibilities, and requirements can take as long as two months.

Important issues to resolve and to discuss during this step include the following:

• Verification of the consignee contact information, titleholder, and marking requirements (obtained as part of Step 3) with the procurement agent or clearing agent, as appropriate
• Development of a scope of work for the clearing agent on the basis of the list of requirements, including monitoring shipment progress, obtaining Value Added Tax waivers or exemptions, ensuring cold chain storage (if necessary), and arranging for clearance and delivery of the goods
• Identification of in-country companies to clear customs and to transfer commodities to the warehouse (The process for selecting clearing agents should follow contractual requirements, if necessary [e.g., DELIVER’s contract requires a minimum of three quotations] and should include visits and inspections to potential contractors and agents, if possible.)
• Finalization and issuance of the contract with the clearing company

It is important to note that, without a signed waiver and approvals, you cannot legally enter any procurement contracts with manufacturers.
STEP 9. NEGOTIATE AND ISSUE CONTRACT TO MANUFACTURERS.
When selected procurement tasks have been outsourced by the organization to a procurement agent, a particularly important communication link exists between the organization, the procurement agent, and the manufacturer. It is extremely important that roles and responsibilities are clear and that communication is well defined. This clarity of roles and responsibilities is usually undertaken through manufacturer contracts. DELIVER’s experience has shown that the entire contract negotiation process can take between one and two months.

Given the specialized expertise and the attention to detail that are required in this step, DELIVER typically assigns responsibility to a single person for reviewing and issuing the manufacturers’ contracts. Important elements to pay attention to when reviewing the contract include payment and indemnity clauses, plus any in-country delivery and clearance issues. Once agreement has been reached, the procurement agent issues the contract to the manufacturer. It is important to note that the contract can be issued only after approvals are received from OAA.

Both before and after issuance of the contract, constant communication is a key element to ensuring timely procurement. Items that should be discussed or reviewed regularly include potential changes in commercial item contracts and in final shipment schedules, which are compared to the original manufacturer contracts.

STEP 10. PLACE COMMODITY ORDERS.
Commodity orders can be placed with manufacturers after all approvals have been received from OAA, after the money is received from USAID, and after the contracts are issued to the manufacturers.

Any advance partial payments that were negotiated in the contract should be followed up and, if necessary, shipment schedules should be updated to avoid delays. If updates and changes in delivery quantities or dates occur, those changes should be shared with recipient country partners as soon as possible.

STEP 11. MONITOR SHIPMENTS AND DELIVERY PROCESS.
Monitoring progress of the procurement process is an important element in minimizing delays and bottlenecks. The commercial items contract and routine reports from the procurement agent can be useful tools to monitor the procurement and to enable coordination between the key partners. A minimum of a three-month lead time should be factored in from the time the order is placed until the arrival of the commodities in-country.

STEP 12. RECEIVE COMMODITIES AND PAY MANUFACTURER.
The receipt of goods in-country is often accompanied by documents that are required for final payment to the manufacturer. Once goods have been delivered, as per the contracts and agreements, the DD 250 receiving form should be completed and returned to the project as rapidly as possible. The documents serve as confirmation and as verification of delivery. Once delivery is confirmed, payment to the manufacturer can be made on the basis of the terms of the contract.
CONCLUSION

The increased availability of USG funds for expansion of HIV/AIDS programs and services through the PEPFAR program has resulted in an increased demand for HIV/AIDS commodities, including ARV drugs, HIV test kits, and laboratory supplies. At the same time, given the pressures countries and programs are facing to scale up services and the complexity associated with using USG funds for procurement, Ministries of Health and other programs that receive USG funds for commodity procurement requested existing supply chain partners, such as the DELIVER project, to assist with procuring HIV/AIDS commodities. Although not originally tasked with a mandate for commodity procurement, USAID Missions requested that DELIVER assume this role in the short term to enable programs to meet treatment goals.

This guide outlines the lessons and processes learned over the course of DELIVER’s experience in procuring HIV/AIDS commodities. It speaks to the complexity of the process, which involves various waivers, approvals, and steps required for successful and timely procurement. The guide also highlights the increasing number of actors involved in procuring HIV/AIDS commodities including nongovernmental organizations, programs, host governments, multiple donors (at the Mission and headquarters levels), procurement agents, clearing and forwarding contractors, and many others, as well as the environment in which they operate. Most important, however, this guide highlights the importance of developing a clear and transparent procurement process for ensuring that continuous supplies of quality HIV/AIDS products reach customers.
REFERENCES


Many of these steps occur simultaneously. This table is a general framework for when steps should occur and how they might overlap.

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<th>STEP</th>
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<td>Month 1</td>
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<tr>
<td>1</td>
<td>Obtain Mission approval</td>
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<td>2</td>
<td>Validate quantities to procure and develop a procurement plan and shipment schedule</td>
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<td>Gather relevant information and compile documentation.</td>
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<td>Prepare and issue task order</td>
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<td>5</td>
<td>Evaluate information in commodity procurement information table.</td>
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<td>6</td>
<td>Prepare Source and Origin Waiver</td>
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<td>7</td>
<td>Submit and receive OAA approval.</td>
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<td>Confirm in-country delivery process.</td>
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<td>Negotiate and issue contract to manufacturer</td>
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<td>Monitor shipments and delivery</td>
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<td>12</td>
<td>Pay manufacturers</td>
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GLOSSARY OF TERMS

**action memorandum.** This formal title is given to the blanket waiver.

**AIDAR.** According to USAID, “the AIDAR is USAID’s Acquisition Regulation supplementing the FAR (48 CFR Chapter 1) and is published as Chapter 7 of Title 48, Code of Federal Regulations.”

**Automated Directives System (ADS).** This USAID reference sets out policies and procedures for procurement. Specifically, “ADS 312: Eligibility of Commodities” is relevant to the procurement of pharmaceuticals as “restricted commodities.”

**blanket waiver.** This USAID/OAA document contains a list of products that are pre-approved for procurement by USAID. A blanket waiver also provides approval for restricted commodities. If products are included on the blanket waiver, then there is no need for a separate source and origin waiver.

**CRS.** Catholic Relief Services

**GMP Certificate.** The Certificate of Good Manufacturing Practice (GMP) issued by a regulatory agency, for example the FDA, certifies that a quality approach to manufacturing has been taken in order to ensure that products are safe, pure and effective. The GMP Certificate is issued by the regulatory authority in a particular country or regional body that oversees manufacturing of certain products.

**Code of Federal Regulations (CFR).** Published in the Federal Register, these rules are set by the executive departments and agencies of the federal government. Specifically, 22 CFR, Part 228, Rules on Source and Origin and Nationality for Commodities and Services. The rules are financed by USAID and are relevant for HIV/AIDS commodity procurement.

**cognizant technical officer (CTO).** According to USAID, “the CTO is the individual who performs functions that are designated by the contracting or agreement officer, or is specifically designated by policy or regulation as part of contract or assistance administration.”

**commodity procurement table (CPT).** This procurement plan is specific to each country, with proposed shipment tables. This table is sent to the procurement agent with the final task order.

**commodity procurement information table (CPIT).** This table contains all information required for the procurement process, including product specifications, manufacturing sites, source and origin of products, price per unit, and expected in-country arrival dates. It is attached to the waiver application for OAA.

**contract with manufacturers.** This item has two key components:

**Commercial Items Contract (CIC).** A CIC provides key details of each commodity as contained in CPIT, as well as delivery dates for each item negotiated and agreed to with the manufacturers. The CIC portion of the contract can be amended.

**Standard Terms and Conditions.** This component is negotiated before signing the contract and includes information such as payment methods, marking requirements, quality assurance requirements, etc.

**DD 250 Form.** This form is issued by the procurement agent to a consignee in a country receiving goods. It details the shipment particulars and, after it is signed, provides proof of acceptance.
**EGPAF.** Elizabeth Glaser Pediatric AIDS Foundation

**Incoterm (International Commercial Terms).** These standard trade definitions are most commonly used in international sales contracts. The objective of Incoterms is to reduce confusion over interpretations of shipping terms, by outlining exactly who is obligated to take control of—and insure or not insure—goods at a particular point in the shipping process.

**manufacturing site.** This is the place where the products are manufactured (origin).

**marking.** These labeling specifications are for all products procured using USG funds.

**OAA.** The Office of Acquisition and Assistance is within USAID.

**PEPFAR.** The President’s Emergency Plan for AIDS Relief.

**procurement agent.** The agent with whom DELIVER contracts to assist in the procurement of all related commodities.

**procurement agent weekly reports.** The procurement agent provides a weekly report to DELIVER about the status of the ongoing procurement process in all of the countries.

**PSCM.** This is the partnership for Supply Chain Management

**restricted commodities approval.** This approval is from OAA to procure pharmaceuticals that are classified by the USG as “restricted commodities.”

**request for task order proposal (RFTOP).** This request is a process whereby the scope of work for a specific procurement is defined in order for an outsourcing purchasing agent or agency to be able to provide the level of effort and cost for the procurement before issuing a task order.

**source and origin:**

**source.** This term refers to the country from which a commodity is shipped to the cooperating country, or to the cooperating country if the commodity is located there at the time of the purchase. However, if a commodity is shipped from a free port or a bonded warehouse in the form in which it is received, source then means the country from which a commodity was shipped to the free port or to the bonded warehouse.

USAID considers a **bonded warehouse** to mean any duty-free area (e.g., export processing zone or an entire country if the country imposes no duties or taxes on drugs).

**origin.** This term is the country where a commodity is mined, grown, or produced. A commodity is produced when—through manufacturing, processing, or substantial and major assembling of components—a commercially recognized new commodity results that is significantly different in basic characteristics or in purpose of utility from its components. For our purposes, the site where the drug, HIV test kit, or reagent is manufactured is the country of origin.

**Source and Origin Waiver.** This document is an approval from OAA to procure commodities from sources and origins not included in the blanket waiver.

**unit size.** This term is the basic unit of the product (e.g., tablet, capsule, test, etc.).
HIV/AIDS COMMODITY SECURITY

A FRAMEWORK FOR STRATEGIC PLANNING

The author's views expressed in this publication do not necessarily reflect the views of the United States Agency for International Development or the United States Government.
DELIVER

DELIVER, a six-year worldwide technical assistance support contract, is funded by the President's Emergency Plan for AIDS Relief (PEPFAR) through the U.S. Agency for International Development (USAID).

Implemented by John Snow, Inc. (JSI), (contract no. HRN-C-00-00-00010-00) and subcontractors (Manoff Group, Program for Appropriate Technology in Health [PATH], and Social Sectors Development Strategies, Inc.), DELIVER strengthens the supply chains of health and family planning programs in developing countries to ensure the availability of critical health products for customers. DELIVER also provides technical management of USAID’s central contraceptive management information system.

Recommended Citation

Abstract
An effective response to HIV/AIDS demands multisectoral and multi-programmatic action. HIV/AIDS programs, including ART, PMTCT, VCT, and PEP, require a vast number and range of commodities. Ensuring that customers can obtain and use these commodities when and where they need them, otherwise known as commodity security, requires an effective supply chain. In addition, commodity security also requires a coordinated strategy to address programmatic elements and cross-cutting issues, such as leadership and effective policies. This paper presents the HIV/AIDS commodity security framework, which provides a model that brings together all of the programs, functions, and cross-cutting issues that must be addressed when developing a strategy to ensure continuous availability of HIV/AIDS commodities.
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# Abbreviations and Acronyms

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AIDS</td>
<td>acquired immune deficiency syndrome</td>
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<tr>
<td>ART</td>
<td>antiretroviral therapy</td>
</tr>
<tr>
<td>ARV</td>
<td>antiretroviral</td>
</tr>
<tr>
<td>HIV</td>
<td>human immunodeficiency virus</td>
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<tr>
<td>IEC</td>
<td>information, education, and communication</td>
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<tr>
<td>OI</td>
<td>opportunistic infection</td>
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<tr>
<td>PEP</td>
<td>post-exposure prophylaxis</td>
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<tr>
<td>PMTCT</td>
<td>prevention of mother-to-child transmission</td>
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<tr>
<td>QA</td>
<td>quality assurance</td>
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<tr>
<td>STI</td>
<td>sexually transmitted infection</td>
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<tr>
<td>TB</td>
<td>tuberculosis</td>
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<tr>
<td>VCT</td>
<td>voluntary counseling and testing</td>
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</table>
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/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/AIDS services. The publication is also dedicated to friends and counterparts who have worked with DELIVER, 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/AIDS and laboratory commodities, we recognize that comprehensive HIV/AIDS and laboratory programs require the supply chain to manage and deliver a broad range of several hundred public health commodities.

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Introduction

An effective response to HIV/AIDS demands both multisectoral and multiprogrammatic action, with a variety of programs that address prevention, treatment, and care, all with appropriate links between them. These programs—including antiretroviral therapy (ART), prevention of mother-to-child transmission (PMTCT), voluntary counseling and testing (VCT), post-exposure prophylaxis (PEP), blood safety, sentinel surveillance, and palliative care—require a vast number and range of commodities. Those commodities include antiretroviral (ARV) drugs; drugs to treat opportunistic infections (OIs); HIV test kits; laboratory reagents; medical consumables such as syringes and gloves; and information, education, and communication (IEC) materials.

One of the major constraints in the scale-up of successful national HIV/AIDS programs is the inability of the national program to make available the commodities needed. Ensuring that customers can obtain and use these commodities when and where they need them—also known as commodity security for HIV/AIDS programs—requires an effective supply chain. But an effective supply chain on its own will not provide HIV/AIDS commodity security. It also requires effective service delivery and other programmatic interventions, such as IEC, and the existence of a supportive policy, legal, and social environment.

Just as the supply chain is only as strong as each of its components—selection, forecasting, quantification, storage, distribution, inventory control, monitoring, and financing—the provision of HIV/AIDS services depends on each of its programmatic elements as well as on cross-cutting issues, such as leadership and effective policies. Overall commodity security for the people who use HIV/AIDS programs and services rests on the interplay among all of these elements. Without an effective coordinated strategy to address all of these issues, HIV/AIDS commodity security cannot exist. Equally, effective implementation of those policies must exist across all aspects of HIV/AIDS programming, including the supply chain, to ensure that HIV/AIDS commodities are available and accessible when and where they are needed. A commodity security approach, which looks beyond the immediate supply chain functions such as forecasting, procurement, and distribution, is needed to ensure commodity availability. As an illustration of the interplay among all these elements, the HIV/AIDS commodity security framework provides a model that brings together all of the programs, functions, and cross-cutting issues that must be addressed in developing any strategy to ensure continuous availability of HIV/AIDS commodities.
A Framework for HIV/AIDS Commodity Security

The availability and accessibility of quality HIV/AIDS commodities rest on the interplay of a series of functions, programs, and activities. The HIV/AIDS commodity security framework (figure 1) brings together these elements and provides a starting point for developing a strategy for HIV/AIDS commodity security.

The framework is presented as a series of concentric circles, with the desired outcome—that customers can obtain and use the needed commodities—as the center, or bull’s-eye. That central point is what we call commodity security for HIV/AIDS programs: where customers—both service providers and, ultimately, patients—can obtain and use the HIV/AIDS commodities they need, whether they are drugs, reagents, test kits, contraceptives, or consumables, when and where they need them.

Obviously, the diversity of programs implies a wide range of commodities from drugs to laboratory reagents. The commodity package triangle (figure 2) highlights some of the types of commodities needed.

As noted, an effective national HIV/AIDS effort requires three different categories of programs: prevention, treatment, and care, which are shown in the innermost circle of the framework. Within each category, several types of programs will exist, and the environment must support commodity security for this diverse range of programs. Under prevention, programs could include PMTCT, VCT, OI treatment, blood safety, sentinel surveillance, and condom distribution. Treatment programs

Figure 1.
HIV/AIDS Commodity Security Framework
could include ART and PEP, while care will include palliative care and tuberculosis (TB) treatment. Note that many of these programs will overlap the general categories; OI treatment, for example, can be considered as both prevention and care. These programs are the interface by which clients obtain and use HIV/AIDS commodities and services. The types of programs available will vary with the particular epidemic in a given country and the resources available. Each program may involve various sectors—public, commercial, and not-for-profit.

The next circle depicts the programmatic functions that must be fulfilled. All of the programs in the innermost circle require most or all of these functions. They include the supply chain (logistics) with its individual elements (figure 3), service delivery to end users, and IEC.

The next circle in figure 1 depicts the cross-cutting issues that affect all programs and, hence, commodity security. The framework addresses six critical cross-cutting issues: the necessity for leadership at all levels, the availability of sufficient financing for all aspects of programming, coordination between all stakeholders, the quality of all commodities and services, the existence of adequate monitoring and evaluation for all activities, and the availability of adequate human resources for all functions. Finally, the whole framework rests within a policy, sociocultural, and socioeconomic environment that affects everything and that must be considered for every intervention. This environment is represented in the outermost circle of the framework.

The complexities involved in developing a national response to HIV/AIDS have seen much emphasis on improving coordination (box 1). The development of the “Three Ones”—one agreed framework, one HIV/AIDS coordinating authority, and one agreed monitoring and evaluation system for each country—has been
one product of that effort. HIV/AIDS commodity security should be part of this coordinated approach. An HIV/AIDS commodity security strategy should support any existing national strategic framework and complement any other strategic plans, for example, in areas such as quality assurance (QA) or service delivery. Depending on the circumstances, commodity security strategy may be part of another broader strategy or a standalone document that references and supports other strategic plans. The breadth of issues to be considered to ensure HIV/AIDS commodity security does not mean that a plan needs to explicitly address in detail each of those areas. For instance, it could focus on the supply chain if other functional areas are included in other detailed strategies.

Box 1.
The National Strategy in Ghana

As in most developing countries, Ghana’s national HIV/AIDS response is guided by a national strategy, the National HIV/AIDS Framework. The current framework covers the period 2001–2005, and a new framework for 2006–2010 is being completed. This framework identifies priority issues and strategies. Ghana is currently developing an HIV/AIDS commodity security strategy to address specific commodity-related issues, and this strategy is intended to complement and be subordinate to the National HIV/AIDS Framework. Ghana also has several other related strategies, such as a plan to address human resource issues, and the commodity security strategy will also complement those strategies.
HIV/AIDS Commodity Security: Obtain and Use Commodities

The ultimate goal of HIV/AIDS commodity security is that customers can obtain and use the quality commodities they need when and where they need them. Customers include both end users and intermediate users—in other words, the medical staff members (doctors, nurses, pharmacists, technicians), and others who use, prescribe, or dispense the commodities. A point worth highlighting is that the total list of HIV/AIDS commodities needed for an effective ART program includes a lot more than just ARV drugs. Policymakers and program managers have identified the need for an integrated approach to HIV/AIDS prevention, treatment, and care—with effective programs for all three. Thus, a full range of commodities to support all programs is needed. Commodity security for HIV/AIDS depends on the availability of all commodities for all types of programs (box 2).

Figure 2 illustrates the types of commodities needed to support programs that deal with HIV/AIDS prevention, treatment, and care. The pyramid does not imply that any one category is more important than another; rather, it reflects loosely the order in which the various commodities have been made available, in turn following the order in which HIV/AIDS programs historically have been implemented. At the base of the pyramid are condoms and other products for prevention, followed by test kits for HIV testing and drugs for treatment of sexually transmitted infections (STIs), PMTCT, and palliative care. At the apex are the ARV drugs needed for providing ART. For each category, associated needs exist for laboratory reagents and consumables. An effective national program needs all of these types of commodities. Each constituent program will not need them all, but it will need at the very least to be able to refer clients to programs where they can obtain such commodities. The items mentioned in figure 2 are illustrative; noting here exactly all of the commodities needed would be impossible. The exact product mix needed will be determined by the epidemiological profile in a country or area; the available financial resources; staff availability and capacity; and supply chain, laboratory, and service delivery capacity.
HIV/AIDS Programs

A comprehensive response to HIV/AIDS involves a wide range of programs, and linkages and synergies between those programs. And although not noted in the framework, each program may include more than one sector—public, private, nongovernmental, faith based, and so on. Within each program will be various support services, one of which is laboratory services.

The initial focus of HIV/AIDS interventions in developing countries was on prevention and palliative care, including treatment of (some) opportunistic infections. The importance attached to HIV testing drove the development of easy to use, cheap and quick HIV “rapid” tests and the subsequent roll-out of VCT programs for HIV. This focus on prevention (including testing) and care was for economic and practical reasons. Treatment was expensive, and developing countries were thought to lack the infrastructure and capacity to offer treatment. Rapid and steep decreases in the prices of ARV drugs brought them within the financial reach of more countries, and innovative treatment programs showed that treatment could be offered successfully in resource-constrained settings. Apart from the moral imperative to offer treatment, public health experts and health economists recognized both a public health imperative, in that the availability of treatment meant people were more likely to seek to know their HIV status and to practice safer behavior, thus reducing HIV incidence, and an economic imperative, in that treatment could prolong the productive lives of those infected—often among the most productive members of society.

Now, most experts recognize the necessity of an integrated approach in offering HIV prevention, treatment, and care services. If treatment is not available, prevention efforts are compromised because people are reluctant to undergo testing to find out their status. PMTCT programs are more successful when they can also offer treatment, while rapid scale-up of ART is impossible unless people are tested. Mirroring this need for comprehensive programs, overall HIV/AIDS commodity security for a country can be achieved only when each program achieves commodity security, and any commodity security strategy needs to address all HIV/AIDS programs and commodities.

Programmatic Functions

HIV/AIDS commodity security depends on capacity existing in certain programmatic areas. The framework highlights three main areas—supply chain (logistics), service delivery, and IEC—though others may exist. Although the supply chain obviously has the most direct effect on commodity availability, decisions made in the other programmatic areas—or not made, as the case may be—have consequences for commodity security and must be considered in that context. It is beyond the scope of this paper to consider all the complexities of, for example, HIV/AIDS service delivery. Rather, we will show briefly how these three functions can affect HIV/AIDS commodity security.

Supply Chain Functions

A well-functioning supply chain capable of selecting, forecasting, quantifying, financing, procuring, and delivering the commodities needed is a prerequisite for any effective HIV/AIDS program. In itself, the supply chain is not sufficient to
ensure commodity security, but without it the other investments made in service delivery, IEC, and policy are not going to achieve their intended program goals. Like any other chain, the supply chain is only as strong as its weakest link. HIV/AIDS commodity security depends on each of the following elements of supply chain management:

- Selection
- Forecasting
- Procurement
- Finance
- Inventory management (including storage and distribution)
- Logistics management information system (including monitoring and evaluation)

The supply chain is likely to be the main focus of any commodity security initiative. When focusing on the technical aspects of the supply chain, we must also consider some of the cross-cutting issues noted in the framework, either as part of the supply chain or separately. For instance, policy barriers may exist to implementing technical solutions on procurement. Or insufficient financing may be available for supply chain functions.

**Service Delivery**

Simply providing commodities does not guarantee commodity security. Adequate service delivery ensures that clients receive the commodities they need along with adequate information and supportive services from trained providers, all in a proper environment, leading to proper use.

The goal of the supply chain is to respond to the changing need for commodities at the service delivery level—to provide the right commodity, in the right place, at the right time. Thus, the pattern of prescribing and dispensing commodities at the service delivery level affects the effective implementation of a supply chain for those commodities. Using standard treatment guidelines not only helps quality of care but also makes forecasting, procurement, and resource mobilization much easier. If no standard organizing system exists for identifying, enrolling, and treating people living with HIV/AIDS, then the pattern of supplying commodities will be unpredictable and inconsistent across regions. Access to care will be inequitable, and forecasting will be difficult as people move locations to find more favorable treatment. Therefore, a clear national policy that provides consistent, orderly, and equitable standards for delivery of HIV/AIDS services and care is important.

Furthermore, related health care services, such as VCT and TB, STI, and OI prevention and treatment, also affect the supply chain. Some activities can stimulate additional demand for commodities that falls outside of normal forecasting; a large HIV prevention campaign, for example, can increase demand for ART. Some activities share the same products, such as HIV test kits, which are needed for both VCT and ART. Still other services can reveal disease trends, such as an increase in HIV as seen through higher STI prevalence or increasing drug resistance through increased cases of OI. Because these services often operate independently, policies should exist to motivate these services to share information, plan together, make referrals to each other, and even share procurement of identical commodities.
A Framework for HIV/AIDS Commodity Security

Information, Education, and Communication
Although providing quality commodities and services could be considered the key interventions for HIV/AIDS commodity security, communications and education activities are also critical. Just to give one example, client education about ART is essential to ensure proper treatment adherence and optimal treatment outcomes. Otherwise drug resistance can emerge, and inconsistent demand can cause over-supplies or commodity stockouts. IEC is also one of the mainstays of HIV/AIDS prevention campaigns.

IEC is not just about client, or patient, education. It includes providing information to caregivers, communicating to all stakeholders on their roles and responsibilities, advocating for resource mobilization, and so on. To ensure the necessary institutional and public support for the supply chain of HIV and ART commodities and for the provision of HIV and ART services, all stakeholders must understand and receive communication about the priorities and policies of national programs. Without this communication, stakeholders may be unable or unwilling to provide the supportive behavior necessary to enable the supply chain functions to operate smoothly.

Cross-Cutting Issues
A range of issues that underpin and support all of the programs and functions previously noted must be considered to ensure HIV/AIDS commodity security.

Financing and Resource Mobilization
Policymakers need to ensure that adequate financing is dedicated to all programs and functions. Financing of the commodities is important but not sufficient. For commodity security, adequate resources must be devoted to infrastructure, capacity, and human resources at all levels and for all programs. Unless the supply chain is adequately financed, commodities will not get to the people who need them; or if resources are not devoted to IEC, then adherence efforts will be compromised.

In terms of resource mobilization, policymakers and program managers need to carefully consider their available resources over the short and medium term and decide on the numbers of clients to enroll in programs accordingly. The consequences of being unable to finance commodities for all patients enrolled are severe. Decision makers must weigh the need to offer life-saving treatment over the short term to as many people as possible against the necessity to sustain treatment over the medium and long term for those who are put on treatment.

Forecasting for HIV/AIDS commodities can provide useful advocacy tools for policymakers, identifying funding gaps and quantifying financing needs that can then be presented to technical partners.

Coordination
Most countries face a complicated system of programs and supply chains for HIV/AIDS commodities. They serve multiple vertical programs with independent procurement, storage, and distribution functions, in public, private, and nongovernmental organization sectors. As a result, ensuring an effective supply of commodities as part of the national response to HIV/AIDS is very difficult and requires a
clear policy of concerted coordination between the programs in all sectors. In addition, to ensure that the supply chain and programs meet the needs of all stakeholders, they must participate in this coordinated effort.

Coordination involves all sectors (public, commercial, not-for-profit, and others) and all stakeholders (ministries, donors, civil society, nongovernmental organizations, and corporations). Obvious benefits accrue to national programs in having cooperation and sharing of information between the private and public sectors. For instance, by including service statistics from the private sector, policymakers and public health experts can obtain a better understanding of the epidemic in their country. Better international advocacy can take place, and there are potential benefits in procurement, service delivery, training, and resource mobilization. Because those benefits may be mainly for the national program and may not be evident or immediate enough for the private sector, creating incentives for this cooperation, or at least removing obstacles, is important. Possible incentives include access to subsidized commodities, training, or access to treatment guidelines. National programs may also elect to enlist cooperation through legislation and regulation, although if the programs lack the capacity to enforce those regulations, they may prove counterproductive.

**Quality Assurance**

Quality assurance is a necessary function of both the supply chain and of all other program elements and, as such, can be a cross-cutting issue. In terms of the supply chain, QA can be considered as the sum of all the policies and practices that ensure the quality of the commodities entering and moving through the logistics cycle. QA ensures that the right commodity reaches the right place in the right condition. The supply of quality commodities cannot be guaranteed without concrete QA measures. Sound policies are needed for the development and implementation of sound practices. Equally, all other programs and systems need sound QA policies and procedures to ensure that clients get the quality products and services they need.

**Monitoring and Evaluation**

Monitoring and evaluation is a cross-cutting function that is needed for all programs and functions to ensure commodity security. National programs and their constituent functions must be capable of measuring progress and outcomes if they are to ensure that targets are being met and to determine the corrective actions to be taken.

**Leadership**

Only through strong leadership, at all levels, can HIV/AIDS commodity security be ensured. Leadership must begin at the highest levels of government to ensure the development of clear and transparent policies and to provide the resources—both financial and technical—to guarantee their implementation. Without strong leadership, effective coordination will not exist between different programs, different sectors, and different technical partners. Many countries have consolidated the responsibility for coordination of all HIV/AIDS policies in national HIV/AIDS authorities or councils. Such bodies are responsible for working with health ministries (and all other ministries), civil society, and technical partners to ensure a coordinated and comprehensive HIV/AIDS response.
Many countries have decentralized decision making to provincial, regional, and district levels, and there, too, strong leadership is needed. Civil society, religious, and traditional leaders as well as civic organizations must support the national HIV/AIDS response. Leadership and commitment are needed first to develop policies, then to devote the resources needed, and finally to support and follow through on the implementation of those policies. Without that commitment, HIV/AIDS programs and the strong supply chains that support them cannot be developed or sustained.

**Human Resources**

Human resources—or the lack thereof—is probably one of the greatest constraints facing HIV/AIDS programs in developing countries. Countries have problems finding, training, and retaining skilled medical personnel. If personnel are insufficient to dispense the commodities supplied or maintain the forms required to track their use, the supply chain and commodity security will be compromised.

All stakeholders need to address the human resource problem to achieve their goals. This issue applies to all programs and functions. As with HIV/AIDS commodities, the focus initially is often on training ART providers, with a later realization that ensuring commodity security also requires the training of support staff members, such as supply chain managers and laboratory personnel.

**Environment**

HIV/AIDS programming does not exist in a vacuum; rather, it is affected by and in turn affects a complex policy, legal, and socioeconomic and sociocultural environment.

**Policy Environment**

National policies and regulations have consequences for the ability of programs to provide HIV/AIDS commodities and services. Some policies may be supportive, whereas others may act as barriers to achieving commodity security. For instance, policies that limit the provision of HIV testing with rapid tests to qualified laboratory technicians can have negative consequences for the availability of testing services in countries where few such staff members exist. Pricing policies for laboratory services can affect uptake of ART. Policies and guidelines on treatment regimens have major consequences for the availability of ART regimens.

**Socioeconomic and Sociocultural Environment**

The broader country environment—from the social factors like the general level of education, to economic factors like income levels, to broader health factors like HIV prevalence—also affects commodity security. Cultural beliefs on disease and health care in general affect all aspects of programming. Adherence levels may be influenced by the degree of social support patients receive. Stigma may affect rollout of various programs. HIV/AIDS programming may need to compete with other national priorities for resources.
Conclusion

An effective and sustainable HIV/AIDS response requires a wide range of commodities supporting a range of programs that encompass prevention, care, and treatment. Each program requires a strong supply chain to ensure HIV/AIDS commodity security—that is, to ensure that HIV/AIDS commodities can be obtained and used when and where they are needed. However, supply chains alone cannot ensure HIV/AIDS commodity security. A framework for HIV/AIDS commodity security shows how the supply chain works with programmatic functions such as service delivery and IEC. Each element of an HIV/AIDS program, including the supply chain, must be underpinned by a supportive policy environment, adequate financial and human resources, a legal framework, and an institutional environment that sustains and supports the program. And there must be leadership and commitment from all to implement policies and programs. A commodity security approach to HIV/AIDS commodities can be an important tool in ensuring the success of countries’ efforts against the HIV/AIDS pandemic by helping guarantee the availability of commodities over the short and long term.
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A Framework for HIV/AIDS Commodity Security


ASSESSING SUPPLY CHAINS FOR HIV/AIDS COMMODITIES
DELIVER
DELIVER, a six-year worldwide technical assistance support contract, is funded by the President's Emergency Plan for AIDS Relief (PEPFAR) through the U.S. Agency for International Development (USAID).

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Recommended Citation

Abstract
This paper serves as a technical resource for assessing supply chain management systems for HIV/AIDS programs in the context of system design, implementation, and monitoring and evaluation. While many tools and indicators for the various types of assessments will remain relatively standardized across commodity groups, including forecasting and monitoring and evaluation for the purposes of system design, a number of key differences exist for HIV/AIDS commodities, notably in the types of assessments, the special considerations during the process, and the frequency and follow up of assessments. This paper serves as a guide for advisors and in-country partners to understand the various types of assessments that are undertaken to measure or monitor system performance, the purpose behind the different assessments, and the tools that are appropriate and valuable to use in the different circumstances.
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### Abbreviations and Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>AIDS</td>
<td>acquired immune deficiency syndrome</td>
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<tr>
<td>ART</td>
<td>antiretroviral therapy</td>
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<tr>
<td>ARV</td>
<td>antiretroviral</td>
</tr>
<tr>
<td>ATLAS</td>
<td>Assessment Tool for Laboratory Services</td>
</tr>
<tr>
<td>FEFO</td>
<td>first-to-expire, first-out</td>
</tr>
<tr>
<td>HIV</td>
<td>human immunodeficiency virus</td>
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<tr>
<td>JSI</td>
<td>John Snow, Inc.</td>
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<tr>
<td>LIAT</td>
<td>Logistics Indicators Assessment Tool</td>
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<tr>
<td>LMIS</td>
<td>logistics management information system</td>
</tr>
<tr>
<td>LSAT</td>
<td>Logistics System Assessment Tool</td>
</tr>
<tr>
<td>OI</td>
<td>opportunistic infection</td>
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<tr>
<td>PMTCT</td>
<td>prevention of mother-to-child transmission</td>
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<tr>
<td>SCM</td>
<td>supply chain management</td>
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<tr>
<td>SDP</td>
<td>service delivery point</td>
</tr>
<tr>
<td>SPARHCS</td>
<td>Strategic Pathway to Reproductive Health Commodity Survey</td>
</tr>
<tr>
<td>TB</td>
<td>tuberculosis</td>
</tr>
<tr>
<td>VCT</td>
<td>voluntary counseling and testing</td>
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</table>
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/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/AIDS services. The publication is also dedicated to friends and counterparts who have worked with DELIVER, 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/AIDS and laboratory commodities, we recognize that comprehensive HIV/AIDS and laboratory programs require the supply chain to manage and deliver a broad range of several hundred public health commodities.

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Introduction

This paper presents technical guidance for assessing supply chain management (SCM) systems for HIV/AIDS programs in the context of system design, implementation, monitoring, and evaluation. In general, DELIVER's approach and standards for system assessment for HIV/AIDS commodity management follow the same principles as those for other commodities. DELIVER has worked extensively in the past with systems managing contraceptives, essential medicines for primary care, and tuberculosis (TB) drugs. In large part, the tools and indicators developed for those other public health commodities can be used for assessing HIV/AIDS commodity supply chains with little adaptation. Nonetheless, although the tools and indicators will remain relatively standardized across commodity groups, a number of key differences exist between SCM assessments for HIV/AIDS and those for other public health commodities, notably in the types of assessments, the special considerations during the process, and the frequency and follow up of assessments.

This paper serves as a guide for advisors and in-country partners in understanding the various types of assessments that are undertaken to measure or monitor system performance, the purpose behind the different assessments, and the tools that are appropriate and valuable to use in the different circumstances. Furthermore, given the wide variety of types of assessments that are conducted of supply chains for HIV/AIDS commodities, the guide proposes a number of standards to follow in preparing and conducting assessments.

Refer to annex A for more detailed information on standards to follow when conducting assessments. The user guides for the Logistics System Assessment Tool and the Logistics Indicators Assessment Tool are also useful references.
Special Characteristics of ARV Drugs and HIV Tests to Consider during SCM System Assessments

Antiretroviral (ARV) drugs and HIV tests are both relative newcomers to public health logistics systems, and they have particular characteristics that often require making adaptations to the supply chain through which they are managed. The special nature of ARV drugs and HIV tests influences the design of the inventory control and logistics management information systems, the design of the storage and distribution networks, and the process for implementing upstream and downstream functions. Because the programs that use these commodities—for example, voluntary counseling and testing (VCT), prevention of mother-to-child transmission (PMTCT), and antiretroviral therapy (ART)—are still evolving in the way services are provided, assessment teams must have a basic understanding of how the special characteristics of HIV tests and ARV drugs affect supply chain performance, system design, and implementation.

The following commodity characteristics are most pertinent to teams involved in assessments:

• Short shelf lives, which can range from 6 to 24 months. It is not unusual for an HIV test kit with a shelf life of 12 months to reach a service delivery point (SDP) with only 6–7 months of remaining shelf life. In such cases, it is critical to measure the SDP’s ability to effectively manage inventory using the first-to-expire, first-out (FEFO) method during an assessment.

• Necessity for cool storage for some products. Many test kits and ARV drugs need to be stored in temperatures not exceeding 25°C. Although this temperature negates the need for refrigeration at SDPs, temperatures often exceed 25°C in many SDPs, and assessment teams must have the ability to measure “room temperature” to determine adherence to storage requirements.

• High price, including a significant jump in price when moving from first-line to second-line ARV drug treatment regimens. As a result, in some systems, managers have decided that second-line ARV drug regimens are not routinely stored at SDPs and are ordered only when needed. In such cases, the lack of availability of second-line drugs should not be counted as a stockout.

• High value in prolonging survival for AIDS patients. This characteristic can create incentives for mismanagement and pilferage that go beyond commercial reasons and thus may be harder to identify.

• Treatment and testing protocols that require multiple products from multiple sources to be available simultaneously to provide a service. Multiple products that constitute a usable ART regimen or HIV testing algorithm must arrive from different suppliers at the same time at the central warehouse and then
must be delivered simultaneously to SDPs. When assessing stock availability, assessment teams should evaluate the availability of a regimen of drugs, not just of the individual drugs.

- Dynamic technology for products leading to constantly evolving treatment and testing protocols. In the case of assessments that are geared to produce data for program monitoring, the drugs or tests on the assessment list may need to change from year to year without compromising the ability to draw conclusions. For example, if Capillus is initially used as the screening HIV test and the program changes to Determine for screening, the subsequent stockout of Capillus should not be a problem if Determine is in supply.

- Higher levels of accountability, including special reporting or other documentation requirements either from donors or from manufacturers.

- Greater potential for redistribution of products from one facility to another to prevent the expiration of products before their use and to ensure the continuous availability of products. Although such initiatives often can be seen as a weakness in logistics system performance, in the case of short shelf life and limited supply, the ability to efficiently redistribute with full accountability should be viewed as an asset.

- Limited number of sites authorized to use the products. The number and type of sites that provide HIV testing and ART services will vary from country to country, affecting both sampling methodologies and sample size.

- Limited possibility of substitution in the case of stockouts. Often multiple brands of the same drug will be available at a site, so a stockout of the branded version may not mean a stockout of the drug or regimen if the generic is available. Interpreting product availability results in this context requires knowledge of in-country regimens or testing algorithms and the supply pipeline.

- Failure of HIV tests kits to contain the full range of commodities needed to administer the test. Chase buffer—a critical component for completing the test—may be packaged separately from the tests, as may be other consumables such as pipettes, pipette tips, gloves, lancets, and vacutainers. As with an assessment of availability of an ARV drug regimen, the availability if all products needed for a test should be assessed.

Because of these special characteristics, HIV tests and ARV drugs are often managed through vertical or separate supply chains. Solutions appropriate for other commodity groups, such as contraceptives or TB drugs, may not apply for HIV tests and ARV drugs because, for example, holding large quantities of stock in inventory at the various levels requires significantly more money and increased storage space and increases the risk of pilferage, damage, and expiration.
HIV/AIDS Program Characteristics to Consider during SCM System Assessments

A number of characteristics of the way HIV/AIDS programs are managed and services provided may affect the planning and conduct of SCM of these programs. Such characteristics include the following:

- Different components of HIV/AIDS programs are often managed as vertical programs. Many times HIV tests are managed through one supply chain; ARV drugs are managed through another; and other products for treatment of opportunistic infections (OIs), prevention, and palliative care are managed through other supply chains. Some components of the supply chains may be integrated in some cases. Depending on the scope of the assessment, the advisor may need to assess a number of different supply chains.

- HIV testing may be done at a number of different types of service sites; therefore, HIV test distribution will have a variety of end points. HIV tests may be used in standalone VCT centers, prenatal clinics, labor and delivery wards, and HIV/AIDS treatment centers or through routine clinical care settings. In some programs, HIV tests are administered by the laboratories associated with those sites; in others, the nursing staff at the site itself administers the tests. Those factors will affect how the advisor determines the sample of sites to visit during the assessment.

- In addition, ARV drugs may be provided through a number of different of mechanisms. ART sites may be standalone centers, may be part of hospital outpatient services, may be situated in prenatal clinics doing PMTCT, or may be other types of sites. That factor will also affect sampling for the assessment.

- The number of sites accredited to provide ARV drugs is generally limited in a program. Programs plan for full supply of ARV drugs for a limited number of patients. New patients are brought on as funding is secured for full supply of ARV drugs for those patients. Assessments should take into consideration how this scale-up in number of patients is managed to ensure commodity security for those patients who have started ART.

- HIV/AIDS commodities for a single program may be financed through a number of mechanisms and donors. Depending on those factors, more than one unit may be responsible for procuring commodities for a single program. For example, ARV drugs and HIV tests may be procured by the ministry of health using monies from the Global Fund to Fight HIV/AIDS, Tuberculosis, and Malaria; through a separate Multicountry AIDS Program office using World Bank funds, and by other units using funds from the U.S. Centers for Disease Control and Prevention or the U.S. President’s Emergency Plan for HIV/AIDS Relief. In assessing the efficiency and effectiveness of procure-
ment, the advisor should look at all procurement units applicable to the objectives of the assessment.
Types of Assessments for SCM of HIV/AIDS Commodities

Because of the emergency nature of the global response to HIV/AIDS, many HIV/AIDS programs and program components may not have evolved through a systematic approach to program development. In many cases, patients are started on ART while other HIV/AIDS services that usually would constitute a comprehensive, ideal package of services are not yet available, and the missing components are gradually being patched together either at individual sites or through networks at different levels of the system. At the same time, even though countries may have been early to jump-start national ART programs, many public health managers and stakeholders are still learning what works and what does not as the programs evolve.

DELIVER’s experience is that assessments are conducted frequently, often with other partners with multiple objectives. Many times the purpose of the assessment is merely to determine broadly what is happening at SDPs, and managers can be reluctant to focus overtly on one issue (e.g., supply chain performance) for fear of losing track of what is happening with another key service delivery component (e.g., adherence levels). Management information systems are very immature, if they exist at all, and program managers have access to very limited data of questionable reliability and accuracy on which to base decisions. Because of various factors—including political pressure; high turnover of staff members at SDPs; shortages of human resources throughout the public health system; and movement of drugs between the public, mission, and private sectors—program managers often request assessments with broader objectives than supply chain issues. Furthermore, in some countries, DELIVER has conducted a series of assessments that have grown in scope each time as the focus of the program evolves.

It is important for teams that are asked to conduct assessments to clearly focus on the purpose of the assessment. After the purpose has been determined and shared with relevant partners and stakeholders, the planning process becomes a key factor in obtaining useful and appropriate data and information based on resources available.

Following is a description of types of assessments DELIVER has conducted. For each type of assessment, the context, the purpose and objectives, the appropriate tools for the type of assessment, and some discussion of the lessons learned or approaches that have proven successful are included. Full descriptions of the tools can be found in annex B. Standards for planning and conducting assessments are included in annex A and should be consulted before beginning preparations for any HIV/AIDS commodity SCM assessment.
Assessing Supply Chains for HIV/AIDS Commodities

Assessment for the Purpose of Preparing a Forecast or Quantification of Commodities Required

Context
DELIVER is usually first involved in this type of assessment at the country level, especially for countries new to its services. In many cases, programs have attempted to quantify their commodity needs, but usually that quantification is made on the basis of available funds rather than on the basis of need or by strategically matching proposed targets with available funding, service, and supply chain capacity and the existing pipeline. Few programs to date have implemented a national logistics management information system (LMIS) for HIV tests and ARV drugs that can provide logistics data on which to develop a forecast. As a result, collecting data and performing a supply chain assessment at SDPs are a critical first step in developing a forecast for HIV tests or ARV drugs.

Purpose and Objectives
Such an assessment has the following objectives:

• To obtain actual data and information on key inputs required for the forecast. Ideally, the data should be aggregated from individual data elements recorded and reported from the facility to the national level. Frequently, however, because of the newness of HIV/AIDS programs, systems for recording and reporting key logistics and service statistics or morbidity data that are required for forecasts are still in their infancy. Thus, during the assessment, the focus should be on collecting data on the number of patients on treatment, the number of patients on each regimen, the quantities of each commodity used for a defined time period, the stock on hand, and other information relevant to preparing forecasts.

• To collect sufficient information to inform assumptions related to the forecast in terms of both patterns of regimen use and realistic trends related to scaling up. In the absence of the availability of aggregated national data on commodity use, informed assumptions have proven to be a viable substitute if, in fact, the right resources inform the assumptions. In other words, assumptions that are based on a profile of data from facilities can greatly enhance accuracy of forecasts. Often, collecting the totality of those data for all facilities—especially in high-prevalence countries where a program may have up to 90 facilities—would be impractical, but a small sample of facilities can provide sufficient information to feed into assumptions.

Appropriate Tools
The following assessment tools can be used:

• Modified Logistics Indicators Assessment Tool (LIAT) tables, including a qualitative section on service capacity and scaling up
• LMIS records and reports for HIV/AIDS commodities
• PipeLine software
• ProQ software and the data collection questionnaire from ProQ
Lessons Learned
DELIVER’s experience suggests the following:

• The purpose of facility assessments is not to collect data that are scientifically viable but to collect or validate assumptions required as inputs to the forecast—for example, the number of patients by regimen or the stockout rates of individual drugs or regimens. Thus, a limited number of sites can provide sufficient data if selected carefully. Make sure that at least one type of each SDP is visited (for example, tertiary level, district hospital, health center, stand-alone testing site).

• Reviewing patient and stock records at facilities often is very helpful in providing a sample of trends in numbers of patients by regimen, but data should be carefully interpreted on the basis of the types of sites visited. As an example, trends in numbers of patients by regimen will be very different at a tertiary-level hospital that has been providing ART for several years than at a district hospital that has just begun enrolling patients on ART.

• A key component of several forecasting-related assessments is determining the level of service capacity at facilities to deliver HIV/AIDS services. Often, this component is key in overall assumptions related to target number of patients to test or treat, and assessing it at facility levels has enabled realistic forecasts to be prepared, hence minimizing wastage during procurement.

Assessment for the Purpose of Logistics System Design or Redesign

Context
The request to conduct a system design often follows as a result of the forecasting intervention. During the preparation of the forecast, inputs related to the design of the supply chain must be factored in (e.g., buffer stock and maximum and minimum supply levels). In new programs, these levels may not have been determined, and although a level might be assumed for the purposes of forecasting, programs quickly recognize the need to design a logistics system to manage HIV tests and ARV drugs to minimize the risk of stockouts. Although assessments may have been conducted before a system design, it is likely that none of them were focused specifically on the details that constitute SCM, including lead times; challenges related to capturing, recording, and reporting logistics data; and responsibilities for stock management. Information from an assessment focusing on the performance of supply chain elements is extremely valuable when one is trying to design a logistics system for HIV/AIDS commodities that will effectively meet both short- and long-term needs of programs.

Purpose and Objectives
An assessment of this type has the following objectives:

• To diagnose supply chain strengths and weaknesses
• To gather information on building blocks of decisions that are made and documented during the system design process

Appropriate Tools
The following tools are appropriate:

- Logistics System Assessment Tool (LSAT)
- LIAT
- LMIS
- Assessment Tool for Laboratories (ATLAS)
- Process mapping

**Lessons Learned**

DELIVER found the following to be true:

- The LSAT is very effective in identifying system strengths and weaknesses, highlighting assets on which to build the new system, and pinpointing areas for improvement (see box 1). The consensus process of the LSAT also creates buy-in to the subsequent system design.
- Because HIV/AIDS commodity supply chains may not have been fully established, assessing related systems, such as those for drugs to treat sexually transmitted infections or lab supplies, may be useful in determining which aspects of existing systems can be transferred or used as models for the HIV/AIDS logistics system design.
- The LIAT provides valuable baseline data that can be compared with similar data after a system is designed and implemented (see box 2).
- DELIVER has used process mapping, which allows a more detailed analysis of strengths and weaknesses and enables the identification of unnecessary steps that can be eliminated in processes, thus streamlining supply chains.
- The LMIS may be of limited use for system design or redesign because the LMIS is often the area that needs the most input during the design or improvement process. Should a functioning LMIS be available during the assessment process, it will provide valuable data on the status of stock distribution, order or resupply frequency, lead times, and other components that can inform the design

**Box 1. Using the LSAT for Work Plan and System Design**

In 2001, DELIVER used the LSAT in Tanzania to assess the logistics system for HIV/AIDS test kits to identify weaknesses and areas for improvement. Little logistics data were available, and no standardized inventory control system existed for HIV/AIDS commodities. The LSAT highlighted those areas of weakness and provided qualitative information on procurement, storage, distribution, organizational support, and other areas useful in assessing Tanzania’s health logistics system for test kits.

Using the LSAT results, DELIVER advisors prioritized areas for improvement and developed the Country Strategic and Evaluation Plan. A process-mapping exercise and a redesign workshop were then conducted that resulted in a logistics system design for HIV tests and other health commodities. The LSAT information was instrumental in designing the system, and it continues to assist in monitoring as the system is piloted and implemented nationwide.
process. When the HIV/AIDS supply chain and LMIS have been established, the LMIS should provide ongoing monitoring data as well as data for periodic reassessment.

**Assessment of ART Site Readiness**

**Context**
DELIVER has experience in conducting broad assessments of site readiness to initiate ART services that look beyond SCM and factor in a facility’s overall capacity to provide ART services. Because of the tight budgets that programs have for ARV drug purchases, the high public health risks associated with emergence of drug resistance if ART patients do not receive adequate quality treatment, and the political attention ART programs receive in many countries, program managers in a number of countries have found it useful to assess a site’s ability to perform all critical components related to treating patients with ART. The tool has proven popular because it provides sites and managers with an action plan of what interventions an individual site needs to progress to ART initiation and to expand the quality of services that can be offered. Furthermore, as experience with the tool has grown, national programs have used it to develop national ART site accreditation tools.

**Purpose and Objectives**
An assessment of ART site readiness has the following objectives:
• To determine a site’s ability to provide quality ART services based on minimum standard requirements. The results of such an assessment also provide each site and its managers with action plans for how to progress to the next level of ART service provision, whether that is initiation of services or expansion of the quality of ART services.

• To provide national accreditation standards for ART sites and to ensure that program managers are able to rate different levels of sites across different geographic regions in a comparable way in terms of providing ART.

Appropriate Tools

The following tools are useful in the assessment:

• Tool to Assess Site Readiness for Initiating ART

• Data collection instruments for use with the Stages of Readiness tool—usually an adapted LSAT and LIAT, an ATLAS, and a clinical services assessment tool

Lessons Learned

DELIVER’s experience resulted in the following lessons learned:

• The Tool to Assess Site Readiness for ART is useful for summarizing the findings of the primary data collection tools and for showing site and program managers how best to focus their resources to prepare for or improve ART services. Because the tool measures status of the site in six domains—leadership, clinical services, management and evaluation, human resources, laboratory capacity, and drug management and procurement—the team conducting the assessment should be multidisciplinary and have experience in all those areas. The scope of such an assessment goes well beyond the supply chain.

• Although the Tool to Assess Site Readiness for ART summarizes detailed information on an individual ART site and helps managers determine how to best strengthen an individual site, when implemented at many sites it can give a picture of the general status of a national ART program and guide policymakers and program managers as to how to best channel their resources.

• A group consensus process with local stakeholders and the assessment team is used to score a site on its status in each domain. The process itself is particularly powerful in building commitment to improving each individual site and developing an action plan to do so.

Assessment for Commodity Security Involving a Policy-Level Analysis of Forecasting, Financing, Procurement, and Distribution Capacity

Context

To ensure HIV/AIDS commodity security—in other words, to ensure that clients can obtain and use quality HIV/AIDS commodities when and where they need them—one must look beyond the supply chain functions and consider potential policy barriers to the smooth operation of those functions. DELIVER has considerable experience in combining technical supply chain assessments for reproductive health commodities with policy-level work using the Strategic Pathway to
Types of Assessments for SCM of HIV/AIDS Commodities

Reproductive Health Commodity Survey (SPARHCS) assessment tool. Although no equivalent tool for HIV/AIDS commodities exists as yet, the broad approach described in the SPARHCS tool may prove useful for anybody considering this type of assessment. The nature and scale of national responses to HIV/AIDS mean that in most cases extensive policy-level work has already been carried out, although that work may not explicitly address commodity security. Often, an assessment will consist of studying existing policy and operational documents, supplemented, if necessary, with interviews with key policymakers and program managers. For each supply chain function, one must look at policy, legal, and institutional arrangements that affect commodity security for all the programs and sectors that use HIV/AIDS commodities.

**Purpose and Objectives**
The objectives of such an assessment are as follows:

- To evaluate policy, legal, and institutional arrangements that affect the functioning of the supply chain
- To determine how closely policies for drug selection, procurement, financing, forecasting, distribution, and storage are followed by actual practices

**Appropriate Tools**
These tools have been successfully used:

- LSAT
- SPARHCS assessment tool

**Lessons Learned**
A number of lessons were learned:

- Policy and practice are often at variance; for instance, procurement policy may be quite explicit on product standards, but in practice those policies may not be applied. In some cases, bringing practices in line with policies may be desirable; in others, advocating for policy change to match practices may be better.
- When doing this type of policy analysis, one may find it helpful to consider how policies affect sectors other than the public sector. In many developing countries, most HIV/AIDS care is provided through the public sector. However, the private not-for-profit and commercial sectors also have important roles to play. The nature of HIV/AIDS has meant major efforts to tightly regulate HIV/AIDS activities in the private sector. This policy has many advantages, but it can mean that the needs of those sectors are not fully taken into consideration and should be looked at.

**Monitoring of Logistics System Performance to Make Midcourse Corrections**

**Context**
Logistics systems are in a state of continuous improvement, and annual assessments of logistics system performance are important to inform work planning and
resource allocation, as well as to monitor progress toward achieving the goal of HIV/AIDS commodity security.

**Purpose and Objectives**

Such assessments are performed for the following reasons:

- To evaluate the performance of the logistics system in its ability to ensure a continuous supply of quality commodities by measuring indicators such as stock status, rate of stockouts, accuracy and completion of recording and reporting, as well as to assess the functionality of the components of the logistics system as defined by the logistics cycle
- To indicate areas in need of redesign or improvement
- To inform work planning and resource allocation

**Appropriate Tools**

These tools have proven appropriate:

- LMIS
- LSAT

**Lessons Learned**

DELIVER’s experience shows the following:

- Many assumptions are made in the design of a logistics system—assumptions on lead times, appropriate review periods, level of effort on the part of workers to implement the system, and the like. Close monitoring (monthly or quarterly) of the performance of the logistics system is important when the system is first implemented so that adjustments can be made in ordering and resupply parameters to ensure the ultimate performance of the system. This requirement is particularly important for HIV/AIDS programs, because in such programs, the monetary and life-saving value of the commodities dictates smaller buffer stocks and less tolerance for wastage. In addition, the lack of information on HIV/AIDS commodity supply available in the design process means that assumptions on design parameters may be weaker than for other system design; therefore, more adjustments based on actual experience with the system should be expected.
- HIV/AIDS programs often start with small pilot activities, which are then scaled up to national level. Logistics system performance may change as the number of service sites increases and more is expected of the system. Closely monitored performance is critical so that adjustments are made either to the system parameters themselves or to the level of resources dedicated to implement the system to serve the increasing demand.
- A logistics system works within a given policy and resource environment. As the environment changes, so must the system adapt to the changes. This factor is even more relevant with HIV/AIDS programs, which function in a complex policy and resource environment with many donors or uncertain funding, often many sources of commodities, and a plethora of procurement regulations that may affect the functioning of the logistics system. Although the basic principles of logistics should weather any environmental change, certain
adjustments may need to be made to ensure the optimal functioning of the logistics system.

Testing of Alternative Strategies (Operations Research) to Select and Implement the Most Appropriate Strategies

Context
As HIV/AIDS programs expand, public sector programs likely will develop substantive partnerships with the private nonprofit and commercial sectors to provide services and medicines and also to extend boundaries within the sector of how and where services and medicines are delivered. SCM systems must be agile and flexible to keep pace with these changes and must develop appropriate solutions for each situation. In many countries, the testing of alternative strategies is occurring as programs are rapidly expanding, without a formal operations research framework; in other settings, a more systematic approach to measuring performance of one approach over another is being developed.

Purpose and Objectives
Such testing has the following objectives:

• To use baseline and endline or experimental and control comparisons to test for new or improved supply chain strategies, which can be used for problem identification and needs assessment
• To celebrate successes

Appropriate Tools
Many tools are appropriate for this task:

• LSAT
• LIAT
• LMIS
• ATLAS
• Smart card technology
• Supply chain manager
• Bar coding

Lessons Learned
• Automation of the LMIS, either fully or at central and regional levels, has significantly enhanced the ability of program managers to collect, analyze, and report logistics data on a more timely and accurate basis. Uganda has adapted and continues to adapt Supply Chain Manager for managing HIV tests and ARV drugs; Kenya is developing its own Oracle-based system for use at the central medical store to manage and use logistics data for HIV/AIDS commodities for resupply and forecasting decisions. Automation of data has made it possible to assess system performance more frequently and quickly and respond to system needs and changes.
• In South Africa, John Snow, Inc., (JSI) has partnered with Net1 (the leading provider of smart card technology in the country) and Catholic Relief Services to use smart cards for ART patient and program management. Providers, patients, and supply chain managers use the smart cards, and data are uploaded on a daily basis to a central database. The technology has been selected for its ability to be used in settings without electricity or phone connections.

• In Uganda, the central medical store is exploring bar coding all of the items it stocks for improved inventory management, beginning with essential medicines. The bar coding is intended to enable the central medical store to custom prepackage each facility’s order without significantly increasing the lead time. Thus, order forms for lower-level facilities have been designed with bar codes for each item, so that at the central medical store the order is captured electronically through use of the bar code reader, and a packing list is generated. Cost studies have been conducted to demonstrate the cost improvements from this initiative.

• In several countries, innovative distribution strategies are being explored for both routine and emergency transportation of HIV tests and ARV drugs. In Kenya, distribution of HIV test kits is outsourced to JSI as a local nongovernmental organization, which in turn has arrangements with the Kenya air force to fly the test kits to remote locations that vehicles cannot reach, as part of routine air force operations. Similarly, JSI has a contract with a local courier service to distribute emergency supplies of HIV tests when sites are about to experience a stockout. In South Africa, certain provincial ART sites have direct contracts with local manufacturers, which distribute prepackaged, monthly ARV drug packs directly to the facilities, thus eliminating central and regional warehouses and the distribution pipeline from that scenario.
Annex A

Standards for Preparing and Conducting Assessments

Regardless of the purpose of the assessment or the methodology selected, a number of steps exist that all teams must follow when preparing for and conducting the assessment. Because of the urgent nature and short timeframe of some assessment requests, assessment teams may have difficulty planning for all the details required to ensure quality outcomes of assessments. Thus, the standards proposed in the following list are intended to serve as a sample checklist to be used in the planning process to facilitate the work of the team leader:

1. **Preparatory work:**
   a. Identify the objectives of the assessment and develop a scope of work that is based on the program, the categories of HIV/AIDS commodities to be studied, or both. What is the goal of your study? Which commodity categories will be covered, and specifically which items within each category are important? What data do you plan to collect? What answers do you need to have? What will you do with the data? Is this a facility survey, a system assessment, a quantitative survey, or qualitative survey? The choice of the type of survey (qualitative, quantitative, facility-based) will be affected by your budget, available resources, and objectives.
   b. Prepare a budget for the costs likely to be incurred by the assessment study teams, including travel and accommodations.
   c. Plan for the involvement of appropriate local counterparts as team members. Ideally, the team members should be involved in managing the HIV/AIDS programs or commodities being assessed to ensure buy-in as well as to ensure a basic knowledge of the characteristics of HIV/AIDS commodities. If all team members are not qualified in this manner, team composition should be designed in such a way that at least one team member has sufficient knowledge in this area.
   d. Present the scope of work to counterparts who are involved in or funding the assessment and negotiate the terms.
   e. Secure financing.
   f. Review and adapt the assessment instruments to meet the objectives identified for the assessment, as well as to meet ongoing monitoring needs:
      • Choose a tool to use for the assessment. Review the tool and adapt it with in-country stakeholder input. All of the tools listed in these guidelines may need to be adapted to some degree to meet the specific needs of the country, the products selected, and the particular assessment. For assessments with clearly defined objectives, when using comprehensive tools such as LIATs or LSATs, it is particularly important that the
particular characteristics of the products and program being assessed are considered in adapting the tools.

• Develop a product list with in-country stakeholders. This process is extremely important for HIV/AIDS commodities such as HIV tests or ARV drugs because more than one product is required to provide a full regimen or testing service. For an assessment focusing on product availability, for example, a short list of indicator products is usually selected, and the results are extrapolated for other items the site is supposed to manage. However, in the case of ARV drugs, the list should include all drugs required to complete an entire regimen, not just one drug from the regimen.

• Prepare a list of indicators to be produced from the data collection, a report template of what the output of the activity should look like to ensure that the activity stays on track with the desired outcome, or both. Again, HIV/AIDS commodity characteristics must be considered at this stage. Will the indicator be the availability of a single HIV test or all three tests required to provide results?

• Review and adapt the training curriculum if one already exists for your type of assessment. Previous versions will require adaptation if they were not specific to HIV/AIDS commodities.

• Conduct necessary background research.

  • Review internal and external documents on the country, particularly any reports on previous assessments.
  • Read documents or fact sheets on the products that will be studied to become familiar with their particular characteristics.

• Determine the appropriate sample size and develop the sampling frame of the facilities to be visited. The main purpose of the sampling design is to avoid a convenience sample. Randomly select the facilities as much as possible. To calculate the sample size and select sites:

  • Compile a list of the total number of facilities in the country.
  • Document the total number of each type of facility (warehouse, hospital, SDP) and the location and distribution of facilities.
  • Ensure that all parties involved agree to the criteria for the selection of sites.

  • For a statistically significant sample, use a standard sampling formula, which often yields a large sample size. In case of resource constraints, visit a default number of a minimum of 100 facilities, or 15 percent of facilities, whichever is smaller.

  • Determine the sampling frame by stratifying for each type of facility in the country; evaluators should randomly select sites proportionally within each stratum, without breaking the supply chain between levels. In other words, select higher-level warehouses first; then randomly select districts within selected regions, SDPs within selected districts, and so on.

  • If statistical significance may not be an important consideration, such as with assessments for forecasting, select sample size and criteria for site selection appropriate for the purpose of the assessment. For example, criteria can include geographic considerations (urban, periurban, rural sites); performance level of sites (if sites are known to be good, medium,
poor performers, visiting a sample of each can provide valuable information for system design purposes and forecasting); and type and range of commodities stocked at each site (not all sites are authorized to maintain all commodities).

i. Train and orient assessment team members. Devoting sufficient time to this activity is especially important. Expanding HIV/AIDS programs and service delivery sites makes it difficult to anticipate every question and script it in advance. Without sufficient preparation, if team members have no or limited experience or knowledge of HIV/AIDS commodities, they will not be able to ask appropriate follow-up questions during the assessment.

j. Obtain written or formal authorization for team members to visit facilities (where needed).

k. Prepare itineraries and logistical arrangements for team travel and accommodations.

l. Schedule a meeting to be held at the end of the assessment to present preliminary findings to stakeholders in the country.

m. Field test the tool at one or more accessible health facilities with all team members.

n. Review the results of the field test and discuss final revisions with the study team members.

o. Finalize the assessment tool.

2. **Work performed during the assessment:**

   a. Observe teams conducting data collection at each level of the system being assessed.

   b. Review completed questionnaires to clarify any data inconsistencies. This step is very important to ensure that the study team is collecting complete and accurate data.

   c. Enter the data collected into the chosen database or spreadsheet.

3. **Work performed after the assessment:**

   a. Conduct data analysis, whether quantitative or qualitative. If no formal data were gathered as part of the assessment, ensure that general trends or findings are summarized across all teams.

   b. Ensure data are interpreted within the local context of the program and with specific application to the commodities being assessed. For example, if the person performing data analysis has no connection with the realities of the program, the team leader should ensure that the data analysis results are translated into tangible actions and recommendations appropriate for the program.

   c. Present the preliminary results, conclusions, and recommendations from the assessment to all stakeholders.

   d. Write the report of results, conclusions, and recommendations.

   e. Disseminate the final report to key stakeholders.
Annex B

Assessment Tools for HIV/AIDS Commodity Supply Chain Management

DELLIVER has developed several tools to collect the data required for the assessment, monitoring, and evaluation of logistics systems. The two primary tools are the Logistics System Assessment Tool, which can be used to assess the logistics system of any health program and to monitor progress toward commodity security, and the Logistics Indicators Assessment Tool, which is useful for monitoring logistics system performance, evaluating progress toward meeting objectives, and measuring commodity availability. In addition to the LSAT and the LIAT, DELIVER uses routine data collected by logistics management information systems. The Assessment Tool for Laboratories is a DELIVER tool that can be used to assess laboratory capacity, and the JSI Stages of Readiness tool is useful in assessing a site’s readiness to introduce ART.

DELLIVER has developed a number of quantitative and qualitative indicators to measure the performance of a logistics system. Table B.1 lists the primary indicators collected by applying each tool.

All of the tools and indicators described in the table can be applied for assessing, monitoring, and evaluating supply chains for HIV/AIDS programs with relatively little adaptation. However, some may be more relevant than others, depending on the program’s needs. For example, both the LIAT and the LSAT can be applied to any health commodity supply chain with little or no change, but collecting all of the data in the tools is not necessary. Depending on the indicators identified by the program and the human, financial, and time resources available to conduct a focus group or a facility survey, programs may choose to remove certain indicators and focus on data collection for their key indicators. Additional questions could be designed to address the specific considerations for the commodities required for HIV/AIDS programs, which include the following:

• Security of commodities in all warehouses or storerooms and transportation
• High value of commodities
• Cold chain storage
• Extra training of personnel
• Additional or more thorough supervision
• Comprehensive program requirement of more than 200 commodities
• Prevention of the interruption of service
• Rigid treatment guidelines

The tools in Table B1 above are available through the DELIVER website. More details about each tool are provided below.
### Logistics Systems Assessment Tool (LSAT)

The LSAT is a diagnostic and monitoring tool that can be used to complete an annual assessment or used as an integral part of the work planning process. The information collected using the LSAT is primarily qualitative and is analyzed to identify issues and opportunities and, from those, to outline further assessment or appropriate interventions. As assessments using the LSAT are conducted and analyzed in successive years, the results can contribute to the monitoring, improvement, and sustainability of system performance and can provide critical nonlogistics data that can identify a country's commodity security strengths and weaknesses.

The LSAT can:

- Provide stakeholders with a comprehensive view of all aspects of a logistics system
- Be used as a diagnostic tool to identify logistics and commodity security issues and opportunities
- Raise collective awareness and ownership of system performance and goals for improvement
- Be used by country personnel as a monitoring tool (to learn and continually improve performance)
- Provide input for work planning
The LSAT can be conducted annually or as agreed on, ideally prior to work planning or strategic planning exercises.

There are two methods for data collection:

• Discussion groups are the preferred approach. They involve either (a) a central discussion group and a separate lower-level discussion group (e.g., of district representatives) or (b) a joint discussion group composed of central and lower-level participants. Plan to conduct, at a minimum, one discussion group involving central participants.
• Key informant interviews can be conducted at both the central and lower levels using the LSAT as a guide.

It is highly recommended that the discussion group participants or interviewer and interviewees complete a limited number of field visits. The visits can be made before data collection to sample current circumstances or after data collection to follow up on issues that arise during data collection. The process of using the LSAT can foster capacity building in diagnosis and system monitoring among the assessment group.

Data analysis and development of recommendations and a work plan should take place immediately after data collection. This process should include a thorough review of system strengths and weaknesses in order to develop and prioritize a set of objectives and interventions that will address issues raised during the LSAT exercise. The results of individual components of the LSAT can be scored and an overall composite score can be developed for comparison with subsequent LSAT results.

Each year, the findings from the current and prior years’ assessments should be compared to measure progress. Likewise, the results of interventions and the assumptions that they are based on should be examined so the experience can be applied to the coming year’s work plan.

Among the benefits of the LSAT is that it requires few resources and can be done in a relatively short time (approximately one week). Personnel using the LSAT should have knowledge of logistics and good facilitation skills.

**Logistics Indicators Assessment Tool (LIAT)**

The Logistics Indicators Assessment Tool, a quantitative data collection instrument, is used to conduct a facility-based survey to assess the performance of the health commodity logistics system and the availability of commodities at health facilities. The LIAT can be used to monitor the performance of certain processes involved in the logistics management of health commodities over time, to evaluate certain outcomes of logistics interventions, to provide ongoing supervision and performance monitoring, and to monitor commodity availability.

The data collected using the LIAT can be used to calculate the following core logistics indicators:

• Accuracy of logistics data for inventory management
• Percentage of facilities that receive the quantity of products ordered
• Percentage of facilities that maintain acceptable storage conditions
Assessing Supply Chains for HIV/AIDS Commodities

- Percentage of facilities whose stock levels ensure near-term product availability (stock status)
- Percentage of facilities that experienced a stockout at any point during a given period or at the time of the visit

In addition to being used to calculate those indicators, the data collected can be used to calculate related indicators, such as duration of stockouts and reasons for stockouts. Supplemental questions provide additional information about the characteristics of the supply chain being assessed, such as the use of LMIS information, ordering procedures, transport systems, supervision frequency, and cold chain management.

As a quantitative facility survey, the LIAT can be used to establish a baseline of logistics system performance for future comparison to subsequent LIAT results. Because of the large number of facilities surveyed during the LIAT, it is resource intensive in terms of time, money, and personnel. Although it could, in theory, be used for monitoring purposes if resources were unlimited, in practice it cannot be applied frequently enough to give managers the information they need along the way between baseline and endline assessments. However, portions of the tool can be adapted for more streamlined facility-based surveys to assess stock status, ordering and supervision practices, and other parameters. In addition to logistics knowledge and facilitation skills, personnel conducting the LIAT should have skills in data analysis.

Logistics Management Information System (LMIS)

Information that is collected and reported through a logistics management information system is vital to the functioning of a supply chain. LMIS data are used to forecast future needs, to plan procurement of commodities, to maintain adequate inventories at all facilities, and to ensure routine distribution of orders to service delivery points. Data collected through the LMIS can also be used to routinely assess supply chain performance.

The basic logistics data that must be collected in an LMIS include stock on hand, rate of consumption, and losses and adjustments. Indicators that can be routinely assessed using these LMIS data include the following:

- Stockout rates at any point during a given period
- Supply status or facility performance at ensuring near-term product availability (stock levels between minimum and maximum)
- Rate of loss of product by reason (expiration, damage, pilferage, and the like)
- Frequency of product redistribution
- Accuracy and completeness of reporting
- Frequency of reporting and nonreporting facilities
- Rates of consumption in a given period

Any of those indicators can highlight areas of strength and weakness, either by facility or by administrative level, and can help program managers determine where performance improvement efforts should be directed. The LMIS can be a very effective monitoring tool with periodic review of these data, allowing problems in the system to be regularly detected and improvements made. Some examples of
LMIS forms for HIV/AIDS programs are the Monthly Logistics and New Patient Report, Record for Returning Unusable Drugs, ARV Drug Dispensing Log, and HIV Test Daily Use Log.

Using the LMIS as an assessment tool or for routine monitoring requires a functioning LMIS. Standard LMIS forms should be in use, data should be of good quality, and reporting rates should be high. Because many HIV/AIDS logistics systems do not yet have a well-established LMIS, its use as an assessment tool should be delayed until reliable data are available. When the LMIS is established, use of routine LMIS data for assessment and monitoring requires relatively low resources.

Assessment Tool for Laboratory Services (ATLAS)

The Assessment Tool for Laboratory Services is a data-gathering tool developed by the DELIVER project to assess laboratory services and logistics. The ATLAS, a diagnostic and monitoring tool, can be used for a baseline survey, to complete an annual assessment, or as an integral part of the work planning process. The information collected using the ATLAS is analyzed to identify issues and opportunities and to outline further assessment or appropriate interventions.

The ATLAS is used to analyze the entire laboratory system and includes three questionnaires: central administrative level, intermediate administrative level, and facility (laboratory) level. Depending on the questionnaire, the recommended data-gathering methods include group discussions, key informant interviews, and facility visits. The three questionnaires need to be adapted for the in-country system. The questionnaire for the intermediate administrative level focuses on decentralized logistics functions. In a highly decentralized system, this questionnaire will need to be adapted. For a complete assessment, it is highly recommended that the ATLAS be used for a group discussion at the central level (and intermediate level, if applicable) and for field visits at the facility level.

Assessments using the ATLAS can be conducted and analyzed in successive years, and the results can contribute to monitoring, improving, and sustaining laboratory performance and can provide critical nonlogistics data that identify a country’s laboratory systems strengths and weaknesses.

The ATLAS can be used to provide the following:

- A comprehensive view of all aspects of the laboratory services for stakeholders
- A snapshot of testing capabilities and commodity availability at laboratories throughout the system
- Input for work planning

The ATLAS can be used

- As a diagnostic tool to identify issues and opportunities for each individual laboratory in a given country
- By country personnel as a monitoring tool (to learn and continually improve performance)
- As a means of focusing collective awareness and ownership of laboratory services performance and goals for improvement
The ATLAS provides a comprehensive overview, particularly at the facility level. The baseline data it provides can facilitate performance and process improvement. However, it is preferable to wait until interventions have been implemented before repeating the ATLAS.

Like the LIAT, the ATLAS is fairly resource intensive (time, human, and financial). The assessment team should have skills in facilitation, team management, HIV clinical experience, laboratory expertise, and logistics.

**Tool to Assess Site Program Readiness for Initiating ART (Stages of Readiness)**

Though not a primary data collection tool, this tool was designed specifically for HIV/AIDS programs as a way of measuring a facility’s readiness to introduce or expand ART. After completion of a separate qualitative questionnaire, the tool is used to guide ministry of health and facility personnel to a consensus on site capacity in the following six program domains:

- Leadership and program model
- Services and clinical care
- Management and evaluation
- Human resource capacity
- Laboratory capacity
- Drug management and procurement

Although this tool can also be used to monitor the scale-up of an ART program, it is especially useful in the beginning stages to measure a facility’s capacity and readiness to introduce ART and to identify what areas need additional inputs to be better prepared to provide comprehensive ART to clients on an ongoing basis. Despite the focus of this tool on site readiness to provide ART services, the tool is included in this paper in recognition of the strong links between site readiness and supply chain management. Offering high-quality, comprehensive HIV/AIDS services require that all applicable elements function well.

The tool can be used for site self-assessment or by external reviewers or program directors to assist sites, programs, and donors in identifying areas that need technical assistance and to assist programs in selecting sites for ART introduction and scale-up. It is not meant to present a barrier to sites but rather to offer an opportunity to work toward start-up or scale-up. In some countries, the tool has been used for monitoring, accreditation, and quality improvement of sites already providing ART. The assessment results should be used to develop work plans to start ART-related preparedness activities or to improve existing services for all sites.

Although using the tool itself is not resource intensive, using the LIAT, ATLAS, and clinical services questionnaires can be. The team collecting the primary data and using the Stages of Readiness tool will need skills in facilitation, team management, HIV clinical experience, laboratory expertise, and logistics.

**PipeLine**

The PipeLine software is used to calculate commodity requirements and is a valuable tool for procurement planning and monitoring for health commodities. The
forecasting methodology used with PipeLine and the software itself can be applied to any health commodity. Ideally, data collectors base their forecasts on actual consumption data or, alternatively, on quantities issued from higher-level warehouses or storerooms. Projections using demographic data or service statistics should also be developed as a comparison, especially when logistics data are incomplete or questionable. These forecasts of future requirements can then be used to plan procurement and monitor shipments, set shipping schedules and delivery dates, set budgets, and plan allocations, all with the ultimate goal of maintaining the continuous availability of the key commodities required to run the program.

**Process Mapping**

Process mapping is an information-gathering and analysis tool that can be used to

- Assess and redesign an existing process or system
- Create a new process or system
- Rationalize job assignments

DELIVER has used process mapping to assess in detail the processes of logistics systems so that it can identify inefficiencies and breakdowns and plan for logistics system improvements.

Process mapping focuses on outputs: something that will be created, accomplished, or done. Examples from health commodity logistics include drugs are ordered, drugs are delivered, a report is submitted. Through an interview process, process mapping makes all significant steps visible and charts the way that work is actually conducted (sometimes as opposed to the way that work is “supposed” to be done). This process leads to identifying actual weaknesses that need to be improved, as well as existing strengths that can be built on in a process redesign.

A process map is a tool for conducting a workflow analysis and improvement. It is a diagram that describes the chronological sequence of work steps used to achieve a particular desired outcome or result, including all process steps, inputs, and decisions. Maps can be used in a number of ways to analyze work performance:

- To evaluate how the work activities actually flow as compared with the policies and procedures that were established to describe and ensure the efficiency and effectiveness of the work system
- To connect the personnel, work activities, resources, and location in a process that helps to determine the capability of the process to produce the desired output
- To identify how the suppliers, processors, and customers communicate during the process
- To identify the cross-functional areas of responsibility for activities and decisions
- To identify customer and supplier requirements
- To identify breakdowns in the current system—duplication of effort, gaps, bottlenecks, and so on—and to connect them to their effect on customer requirements and expectations of products or services
- To identify the current time cycle, staffing requirements, logistical support needed, and so on for operating the process
- To identify current strengths and weaknesses of the system in carrying out its purpose to the satisfaction of customers and stakeholders
• To identify major implications for the redesign of the system

Because most work processes are undocumented, process maps are created in a collaborative process through interviews with the personnel who do the work. A cross-functional team is organized to develop the maps. The team should include those who actually do the work of the process; those who manage the process; and, if possible, those who are suppliers to the process and customers of the process.

Process mapping is time and resource intensive. A process-mapping team for a logistics system should have experience in conducting process mapping, facilitation, and logistics system design.
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Assessing Supply Chains for HIV/AIDS Commodities


SUPPLY CHAIN MANAGEMENT OF ANTIRETROVIRAL DRUGS

CONSIDERATIONS FOR INITIATING AND EXPANDING NATIONAL SUPPLY CHAINS

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DELIVER

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Recommended Citation

Abstract
One of the most critical challenges to the global scale-up of ART programs is the effective management of a supply chain for ARV drugs. Ensuring an effective supply chain for ART requires international and national policymakers and stakeholders to develop an enabling policy environment that both encourages best practices and protects against activities that waste public resources or that are dangerous to public health. This paper helps define that policy environment from a supply chain perspective; it outlines important policy issues to consider and makes recommendations that are practical and applicable to program managers and policymakers on the ground. The objective of this paper is to guide countries on how to develop a policy to strengthen supply chain management for antiretroviral drugs, so the countries can ensure continuous product availability, can maximize resources, and can better expand ART programs.
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## Abbreviations and Acronyms

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<th>Abbreviation</th>
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<tr>
<td>AIDS</td>
<td>acquired immunodeficiency syndrome</td>
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<td>ART</td>
<td>antiretroviral therapy</td>
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<td>ARV</td>
<td>antiretroviral</td>
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<tr>
<td>DDA</td>
<td>dangerous drug act</td>
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<td>FBO</td>
<td>faith-based organizations</td>
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<td>FDC</td>
<td>fixed-dose combination</td>
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<td>HIV</td>
<td>human immunodeficiency virus</td>
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<td>HMIS</td>
<td>health management information system</td>
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<td>JSI</td>
<td>John Snow, Inc.</td>
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<tr>
<td>LMIS</td>
<td>logistics management information system</td>
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<td>NEML</td>
<td>National Essential Medicines List</td>
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<tr>
<td>NGO</td>
<td>nongovernmental organization</td>
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<tr>
<td>OI</td>
<td>opportunistic infection</td>
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<tr>
<td>PLWHA</td>
<td>people living with HIV/AIDS</td>
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<tr>
<td>PMTCT</td>
<td>prevention of mother-to-child transmission</td>
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<tr>
<td>PVO</td>
<td>private voluntary organization</td>
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<td>QA</td>
<td>quality assurance</td>
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<td>STGs</td>
<td>standard treatment guidelines</td>
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<tr>
<td>UNFPA</td>
<td>United Nations Population Fund</td>
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<td>UNICEF</td>
<td>United Nations Children's Fund</td>
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<td>WHO</td>
<td>World Health Organization</td>
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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/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/AIDS services. The publication is also dedicated to friends and counterparts who have worked with DELIVER, 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/AIDS and laboratory commodities, we recognize that comprehensive HIV/AIDS and laboratory programs require the supply chain to manage and deliver a broad range of several hundred public health commodities.

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This paper identifies and discusses some key supply chain management considerations for programs to address and plan for as those organizations initiate and expand national antiretroviral therapy (ART) programs. The considerations are based on the experience of John Snow, Inc., (JSI) in supporting supply chain management of antiretroviral (ARV) drugs. The paper is not intended to be a comprehensive guide to supply chain management of national ART programs, given that experience from national programs is still emerging and evidence on which to make firm recommendations either does not exist or is not yet well documented. Supply chain management of other HIV/AIDS commodities that are required to support a comprehensive national ART program was deliberately omitted from discussion in this paper. Considerations for other commodity categories either have been addressed in earlier publications or will be addressed in companion pieces to this paper.

The focus on ARV drugs is not intended to suggest that other HIV/AIDS commodities are any less critical for program scale up or that their management is unimportant. But given the newness of ART programs and the attention ARV drugs have received, it was felt that some interim considerations and approaches for those commodities would be useful for program managers and supply chain implementers. This paper is intended to be a compilation of lessons learned and emerging best practices that will help inform the supply chain management component of ART program expansion. The paper is also a work in progress; it will inform about implementation of supply chain systems as new lessons are learned and will evolve as programs evolve and as new evidence emerges. Thus, comments, feedback, and experiences are welcomed and encourage.
Executive Summary

In the past several years, the global community has converged to provide an unprecedented opportunity to many countries that are struggling with the AIDS epidemic. Through the launch of several global initiatives such as the Global Fund for AIDS, Tuberculosis, and Malaria; the “3 by 5” strategy of the World Health Organization (WHO); and the President’s Emergency Plan for AIDS Relief, resource-poor countries have access for the first time to the financial and technical resources needed to provide antiretroviral treatment (ART) to thousands who are living with HIV/AIDS. Implementation of those large-scale treatment programs, however, is fraught with technical challenges, especially in resource-constrained countries that have been hit hardest by the epidemic.

This paper explores one of the most critical technical implementation challenges: effective management of a supply chain for antiretroviral (ARV) drugs. The supply chain consists of the sequence of functions that are necessary to deliver and effectively provide an uninterrupted supply of the right quality and quantity of ARV drugs and other commodities. Ensuring an effective supply chain for ART requires international and national policymakers and stakeholders to develop an enabling policy environment that both encourages best practices and protects against activities that waste public resources or that are dangerous to public health. This paper helps to define that policy environment from a supply chain perspective; it outlines important policy issues to consider and makes recommendations that are practical and applicable to program managers and policymakers on the ground.

The objective of this paper is to guide countries on how to develop a policy to strengthen supply chain management for ARV drugs, so that the countries can ensure continuous product availability, can maximize resources, and can better expand their ART programs. The paper identifies key issues and considerations that policymakers and program managers must address to implement the enabling policy environment, and it provides a discussion related to each issue to help policymakers understand and navigate the dilemmas and conflicts that may arise in the decision-making process.

The paper lays out 30 policy considerations, which cover supply chain management–related functions, as well as cross-cutting factors. Some key examples include:

1. To enhance the program’s effect and to reduce the risk of drug resistance, policymakers and donors must commit to providing a full supply of ARV drugs for individuals targeted for ART.
2. To implement an efficient, standardized supply chain for ARV drugs, service providers need clear and comprehensive guidelines for ART eligibility and enrollment.
3. Standardizing prescribing and dispensing practices for ARV drugs is critical for
supply chain planning and for promoting patient adherence and rational drug use.

4. Selection of ARV medication, regimens, formulations, and packaging will affect procurement, forecasting, and distribution, and those relevant supply chain issues should be considered in the ARV drug selection process.

5. To be able to coordinate funding and procurement among multiple donors and to ensure uninterrupted supplies of ARV drugs, program managers must prepare medium-term forecasts.

6. To respond quickly and accurately to changes in demand, to supply the correct quantity of quality drugs, and to minimize pilferage and misuse of ARV drugs, the information system involving supply chain management should be designed and implemented before ARV drugs arrive.

7. Program managers can maximize funding that is available for ARV drug purchases by streamlining the pipeline, monitoring inventory levels, and securing transportation and storage facilities.

8. Program managers should develop a medium- to long-term procurement plan to coordinate drug inputs among donors, to identify clear resource mobilization needs, and to leverage competitive strengths in drug purchases.

9. To provide safe, effective, and comprehensive ART services, program managers must purchase and implement effective supply chains for 100 to 200 other commodities in addition to ARV drugs.

10. Identification of gaps in funding, drug supply, and technical assistance could be a significant barrier to ART scale up, especially without a body to oversee, coordinate, and track the resources that have been promised and allocated.

These policy considerations and recommendations are a product of decades of field experience by John Snow, Inc., in assisting countries in the supply chain management of essential health commodities. The considerations are further informed and refined by the DELIVER project’s recent supply chain-related assistance to new and expanding national HIV/AIDS programs in several countries in sub-Saharan Africa and Latin America.
Introduction

Supply chain management of essential health commodities, including high-value medicines like antiretroviral (ARV) drugs, involves a series of activities to guarantee the continuous flow of products from the point of manufacture to the point where they are used by consumers. The supply chain or its functions operate within a management system that provides program managers with data to help determine what types of products are needed, where and when they are needed, and in what quantities. Yet competing priorities for scarce funding devoted to public health programs often result in insufficient financial, human, and technical resources for implementing and strengthening those supply chains. As a result, supply interruptions and shortages of critical health commodities are common in many public sector programs.

Program planners have increasingly become aware of the importance of efficient supply chains. Supply chain managers can increase the quality and reach of public health programs by better ensuring the availability of the products they manage and by using available resources efficiently so that wastage is minimized and accountability is enhanced. Supply chain management consists of a series of functions that must be routinely performed in a synchronized fashion. Once products for a program have been selected and registered for use, quantity requirements must be determined for the short term (one to three years) and the medium term (three years or more). The products then must be procured, must be cleared through customs, and must undergo quality control checks. After the products enter the program’s supply chain, a multilevel transport and storage scheme must be carefully coordinated so that they reach the service delivery points where they can be used. Supply chain data from all levels in the system must reach managers to enable better decision making. The cycle then repeats itself. Those functions and their interdependent relationships are depicted in the supply chain cycle shown in figure 1.

Historically, a number of priority health interventions provided through vertical programs (i.e., those addressing a single public health issue such as tuberculosis (TB), family planning, or childhood vaccinations) have received dedicated financial support from donors for improving their supply chain systems. Many of those vertical supply chain systems in the public sector are more robust than the existing infrastructure for managing essential health commodities. Some factors that have led to their efficiency are as follows:

• A limited number of commodities with few changes in technology or formulation over time
• A commitment to maintaining a full supply of selected products
• A program of sustained and consistent financial and technical support for systems development and maintenance
• Either the use of external procurement mechanisms, which are usually selected
and paid for by donors, or the extensive use of donated products.

- A group of dedicated program personnel whose responsibilities include supply chain management

Recent health sector reform strategies are designed to eliminate the large number of vertical systems in favor of an efficient, integrated structure that is capable of handling all essential health commodities. Although integrated supply systems are technically feasible, implementation in many countries has been fraught with practical difficulties (Bates and others 2000).

The Need for Effective Supply Chains to Support the Provision of Antiretroviral Therapy

Before 2003, governments and donors had been cautious in introducing ARV drugs on a wide scale in resource-limited settings. Many factors contributed to this caution, including the cost of the drugs, limited human resources, and fear of potential negative outcomes associated with delivering those expensive, highly potent, life-saving medications. Although this level of concern has declined, real fears remain. Policymakers and program managers have realized that implementation of effective supply chain strategies can play an important role in minimizing some negative outcomes, including the following:

- Risk of emerging widespread drug resistance among patients as the result of supply interruptions or procurement of poor-quality drugs
- Leakage of ARV drugs from the public sector into the private sector or to other countries, thus disrupting pricing patterns, affecting forecasting and donor support, and increasing the likelihood of drug resistance among patients if the drugs are prescribed or used improperly
- Increased expense to programs that already lack sufficient funds for buying and delivering drugs for essential health problems
The Changes in Priorities in the Context of a Burgeoning HIV/AIDS Pandemic

A combination of factors—including prolonged PLWHA activism, devastating economic and societal effects of the AIDS epidemic, and emergence of new funding sources—have resulted in governments and their funding partners setting priorities for increased and rapid access to antiretroviral treatment in resource-limited settings. During 2003, new funding sources such as the Global Fund for AIDS, Tuberculosis, and Malaria and the U.S. President’s Emergency AIDS Plan released funds geared at scaling up antiretroviral treatment in particular. The World Health Organization (WHO 2003) launched a new strategy titled Treating 3 Million by 2005: Making It Happen. Commonly referred to as the “3 by 5” strategy, its goal is to set a roadmap for providing lifelong ARV drugs to 3 million people who are living with HIV/AIDS in resource-poor countries by 2005. Goals of the president’s AIDS plan include treating 2 million PLWHA, preventing 7 million new infections, and providing HIV care to 10 million people by 2008 (Office of the Press Secretary of the White House 2003).

However, the gap is significant between those targets and the capacity of health and supply chain systems in countries most affected by the HIV epidemic to implement programs to this effect. Current capacity is weak among public sector supply chains for delivering the unprecedented quantities of commodities required for achieving those global targets in most resource-poor settings. Providing an uninterrupted and secure supply of quality ARV drugs and the 100 to 200 other commodities needed for comprehensive HIV care will require massive investments in human, structural, financial, and technical resources, as well as a long-term approach.

Furthermore, the demands for strengthening the existing health system capacity, including supply chain, are often at odds with the pressure from the new funders to demonstrate rapidly increasing numbers of PLWHA on antiretroviral therapy (ART). At least in the short term, it appears that system-building needs will directly compete with purchases of ARV drugs.

As countries scale up ART services, policymakers and program managers can address key considerations identified in this paper as those considerations relate to supply chain management functions and to economic, legal, social, and health issues in the overall environment.

**Key Consideration 1:** To enhance the program’s effect and to reduce the risk of drug resistance, policymakers and donors must commit to providing a full supply of ARV drugs for individuals targeted for ART.

Few resource-limited countries have sufficient financial resources to commit to procuring a lifetime supply of ARV drugs for all people who are clinically eligible for treatment. Therefore, at least initially in many countries, ARV drugs are likely to be undersupplied when compared to demand, assuming that the majority of PLWHA who are clinically eligible for ART would demand the service. The primary goals of many national programs and the global community are to rapidly accelerate the availability of ART services and ARV drugs and to reduce the gap between demand and supply.
Nonetheless, in the interim period, governments and programs will have to develop strategies and policies to determine who receives ART on the basis of national goals and public health, social, and other priorities. The public health approach dictates that once a patient is enrolled in treatment, that person’s drug supply needs to be guaranteed for life to reduce the risk of drug resistance. In other words, ART will not work by providing half the dose of the drugs to double the number of patients or by providing drugs for only half a year of treatment for patients. Countries or programs must identify the number of patients for whom they can guarantee a full supply of ARV drugs for multiple years. In supply chain terms, this identification means that countries will treat ARV drugs as full-supply commodities, although in theory the medications will be in full supply only for a limited number of patients.
Section 1

Serving Customers

The critical purpose of any supply chain, regardless of the commodities flowing through it, is to serve its customers. In the case of antiretroviral therapy (ART) programs, this purpose means ensuring an uninterrupted supply of quality antiretroviral (ARV) drugs to eligible people living with HIV/AIDS (PLWHA) whenever they need them. Specifically, patients need ARV drugs to be present more than 95 percent of the time that they come for resupplies, because more than 95 percent adherence to ART is required for treatment regimens to be effective over the long term. In a twice-a-day regimen, achieving this effectiveness means that less than one dose can be missed every two weeks. Thus, to implement and maintain a supply chain that is focused on the ultimate customer, the national ART programs must design and prioritize interventions around the concept of uninterrupted availability of the ARV drugs.

Key Consideration 2: To implement an efficient and standardized supply chain for ARV drugs, service providers need clear and comprehensive guidelines for ART eligibility and enrollment.

Because ARV drugs procured by national programs and donor partners will, of necessity, be rationed among eligible PLWHAs, policymakers face decisions about how to ration the drugs and at what level the decision should be made for applying the rationing criteria. Trends from a number of countries suggest that after clinical criteria have been considered, the rationing process will be guided by nonclinical factors, including public health, financial, and social considerations. More challenging to these program is the process of determining who makes the decision about which patients are eligible for ARV drugs, and at which level this decision is made. One approach is for the national level to establish clear and comprehensive criteria and guidelines that can service providers can apply within individual facility settings. A more decentralized approach is to allocate quotas by geographic region and to allow facility managers and service providers to set their own criteria for patient eligibility.

Defining comprehensive national guidelines for ART eligibility and enrollment at the central level—so the guidelines can provide standards for service providers or facility managers to apply—offers several advantages. Centrally developed guidelines for ART eligibility can more easily be linked to achievement of public health and national program goals, whereas a decentralized approach might result in a regional specific focus at the cost of broader public health goals. Furthermore, centralizing the decision making for eligibility criteria will reduce the burden on service providers for making life and death decisions and will facilitate effective supply chain management by ensuring that the number of patients receiving ART does not exceed the overall national supply of ARV drugs.

As these guidelines are developed, it is important to foresee the potential implica-
tions for changes in demand for ARV drugs and regimens as they become more widely available and affordable through the public sector. One implication is that the demand that currently being filled by the private sector may switch to the public sector. A scenario that has already been observed in a number of countries is that a significant number of patients already receiving drugs through the private sector will switch to free-of-charge or highly subsidized drugs in the public sector, resulting in an influx of ART-experienced individuals. If the initial supply of drugs is quantified for ART-naïve patients (first-time ARV drug users), such a switch could result in a greater than anticipated need for second-line drugs if the ART-experienced individuals who paid for their treatment in the past were nonadherent or were treated with suboptimal or inconsistent regimens. This category of patients could have higher failure rates than those without prior ARV exposure, which would affect existing forecasts, procurement plans, and overall program costs because second-line drugs tend to be more expensive.

Developing and standardizing a range of eligibility criteria that address these and other related issues is challenging, given the lack of data available to guide policymakers in predicting the effect of specific decisions at this time. Nonetheless, clear operational guidance for service providers and implementers should be developed and adapted over time and as programs evolve.

**Key Consideration 3: Standardizing prescribing and dispensing practices for ARV drugs is critical for supply chain planning and for promoting patient adherence and rational drug use.**

Before the release of funds for expanding the public sector ART programs, much of the ART service provision in resource-poor countries occurred through private for-profit companies, employer-based schemes, nongovernmental organizations (NGOs), or faith-based outlets. In most cases, patients had to pay for ARV treatment regimens. As national public sector programs continue to scale up services, standardized operational guidelines for prescribing and dispensing practices—especially as they relate to affordability—must be carefully crafted. The need for thorough and comprehensive guidelines is not a new consideration and is recognized as a key factor in enhancing rational drug use of essential medicines (box 1). But one finds a number of important supply chain implications when developing prescribing and dispensing guidelines. In many countries, because the ARV drugs are provided in full supply for only a limited number of patients, prescribing and dispensing guidelines can play an important role in ensuring that the drugs are maintained at recommended inventory levels and that shortages, stockouts, and overenrollment of patients are avoided. Also, the guidelines can play a critical part in helping to reduce the risk of intermittent treatment caused by a fragmented drug supply. Evidence from ART service provision in the private sector in Kenya and Uganda demonstrates that when an element of cost recovery or cost sharing exists for ARV drugs, the attendance of patients at clinics to collect their medications fluctuates every month according to their purchasing power.

Thus, it is important to ensure that prescribing and dispensing guidelines address all those issues. At the very least, the guidelines should recommend measures to ensure that regimens are prescribed according to national standard treatment guidelines and that three ARV drugs are always prescribed together and in the correct combination and dosage. Using preprinted prescriptions is one approach
Data collected from one southern African country demonstrates that a total of 48 different ART regimens are prescribed in public sector sites. Six adult first-line regimens are prescribed and are consistent with recommendations in the STGs. However, of the 30 alternate first-line and second-line regimens being prescribed, only 1 is consistent with recommendations from the STGs. Similarly, only 3 of the 12 prescribed pediatric regimens are consistent in STG recommendations.

for enabling good prescribing practices. Not only does this preprinted form ensure consistency with standard treatment guidelines (STGs), but also it reduces the chance of a prescribing error. Correspondingly, dispensers should always dispense the three drugs together and in the correct combination. All guidelines should clearly show that if one of the three drugs is unavailable—unless there is an approved substitute for that drug—then none of the three drugs required for the regimen should be dispensed. Stocking quality, fixed-dose combination drugs or single pills in blister or calendar packs is a simple but effective measure to deal with this problem.

Another important issue that should be incorporated in the STGs is closely related to the quantity of buffer stock or the inventory levels of ARV drugs in the country. The STGs need to offer guidance regarding how frequently prescriptions should be written, how many months or weeks of supply should be dispensed at any one time, and whether prescriptions can be refilled without visits to the physician. Because ARV drugs are expensive, programs are streamlining their pipelines (eliminating levels) and reducing lead times and review periods; thus, they can minimize the quantity of buffer stock that needs to be maintained at facility levels and central warehouses. In some cases, facilities review their stock status and place orders on a monthly basis; they are provided with one month of stock for their existing number of patients and one month’s worth of buffer stock. This arrangement means that patients cannot receive more than one month’s supply of ARV drugs at a time or the facility will not have sufficient drugs to treat all enrolled patients. In sum, STGs should include the following: the length of time prescriptions can be valid, the maximum supply of drugs a patient can receive, and the validation and verification between prescriptions and dispensing practices—among other issues.

A further complication involves programs that implement any kind of cost-recovery mechanism. In such cases, affordability of ARV drugs has already emerged as an issue, with many patients unable to pay for a full month’s supply at one time. Other examples related to affordability include patients requesting cheaper regimens and patients requesting multiple months of supply to save on transportation costs (Uganda Ministry of Health 2004). In Uganda, there is evidence that, in the past, when patients were accessing ART through non-public sector outlets, patients received anywhere from a three-day to a three-month supply, depending on their financial and social circumstances. They did not always obtain one full month’s regimen. Prescribing and dispensing guidelines should take into account the cost-recovery mechanisms and implications on supply chain management.
Key Consideration 4: **ARV drug supplies should be closely linked to the ART service capacity at both the national and facility levels.**
Many countries in the process of scale-up have used the quantity of available funding for drug procurement as one way of setting targets for expansion. Although obviously the quantity of the national drug supply is a key factor in determining how quickly programs can expand, another critical factor that is sometimes downplayed is the capacity of the program or of the health facilities and providers to deliver uninterrupted, safe, and effective care and treatment to the patient, as demonstrated in the example above. Underestimating service capacity and the potential effect of such programmatic, clinical, and financial factors on supply chain management can lead to myriad problems. As an example, overprocuring ARV drugs to meet national targets without taking into account the service’s or facility’s capacity can result in large overstocks of drugs that eventually expire or that leak out of the system, which could lead to withdrawal of funding for ARV drug purchases from donors. This problem is especially true for costly, second-line regimens.

Key Consideration 5: **To ensure uninterrupted, safe, and effective ART service provision, the programs should establish minimum requirements for facilities and should conduct ART site selection and accreditation on the basis of those requirements.**
As a first step toward evaluating service capacity, policymakers must define minimum standards or requirements for providing uninterrupted, safe, and effective ART service. Those requirements can range from very simple conditions (including the presence of trained nurses, clinical guidelines, a secure DDA box, and basic monitoring and tracking records) to very complex situations (such as those found at national referral centers). Then, program managers need to assess the readiness of facilities and providers to offer ART services according to established minimum requirements and to identify critical gaps that may present barriers to providing uninterrupted, safe, and effective ART. The assessments should be rapid and oriented toward immediate results that easily translate into actions for improv-

Box 2. **Service Capacity as a Constraint to Expanding ART**

One country in sub-Saharan Africa conducted a site-specific survey for ART readiness, six to eight months prior to preparing to introduce ARV drugs into the public sector. Results in 14 of 15 sites showed inadequate staffing levels of physicians, nurses, counselors, pharmacists, and laboratory technicians. Most of the existing staff members had not had HIV- or ART-specific training but were caring for PLWHAs because of the widespread nature of the epidemic in the country. The national referral hospital had only 12 of 20 pharmacist positions filled and only 45 of 60 pharmacist technologist positions filled. Only two pharmacists and two pharmacist technologists had received training in HIV and ARV drug management or any in-service training during the past year. Priority training areas identified by the survey included general HIV/AIDS and ART management, quantification, inventory management, and principles of good laboratory management.
Serving Customers

In response to the need for a tool to determine a site’s overall readiness to initiate ART services, John Snow, Inc., has developed an aid titled “Tool to Assess Site Readiness for Initiating Antiretroviral Therapy” (Hirschhorn and others 2004). It provides a comprehensive framework that a program can use for accrediting ART sites for the initiation and expansion of services, and it includes criteria for supply chain management. The tool can help to categorize sites in terms of leadership, management practices, availability of HIV-related services, human resource and laboratory capacity, and commodity supply chain management. This tool has been used in several countries, including Burkina Faso, Ghana, Kenya, Nigeria, Tanzania, Uganda, and Zimbabwe.

At the start of program planning, as programs are determining the location and pace of ART initiation and expansion, the inclusion and development of specific criteria for pharmacy, drug, and supply chain management are critical. Supply chain management criteria should include elements about training, storage, inventory control, record keeping and reporting, as well as measures to reassess sites to ensure that standards are maintained over time. In some countries, the quality assurance of sites is being formalized through an accreditation and certification process. As programs expand, however, implementing formal quality assurance processes will have to be balanced against the immediate needs for delivering ART.
Section II

Product Selection

The World Health Organization (WHO) has developed and updated *Scaling Up Antiretroviral Therapy in Resource-Limited Settings: Treatment Guidelines for a Public Health Approach*, as a guidance for countries to facilitate the proper management and scale up of antiretroviral therapy (ART). In the guidance, WHO proposes a public health approach geared toward universal access, standardization, and simplification of antiretroviral (ARV) drug regimens to support the implementation of treatment programs in resource-limited settings and to ensure that treatment programs using ARV drugs are based on scientific evidence. The goal is to avoid the use of substandard treatment protocols and to reduce the potential for the emergence of drug-resistant virus. As a first step, national committees involved in updating national essential medicines lists (NEMLs) and for developing standard treatment guidelines (STGs) should consult WHO’s recommendations when selecting ARV treatment regimens that are appropriate for their particular country setting.

**Key Consideration 6: Selection of ARV drugs, regimens, formulations, and packaging will affect procurement, forecasting, and distribution, and those relevant supply chain issues should be considered in the process of selecting ARV drugs.**

STGs for ART should provide clear criteria for first- and second-line regimens, for the management of patients experiencing toxicity or failing treatment, and for the treatment of specific subgroups, such as patients with tuberculosis, pregnant women, children, and health workers who require post-exposure prophylaxis. Considerations should include clinical and operational factors such as efficacy, availability, pill burden, toxicities, drug interactions, teratogenicity (such as with efavirenz), and cost. As an example, high pill burdens can often lead to poor adherence; thus, use of fixed-dose combinations (FDCs), where possible, should be clearly specified. First- and second-line ARV regimen choices, as well as formulation (FDCs versus single pills) and packaging decisions, will affect procurement, forecasting, and distribution and should be carefully reviewed and evaluated as the medications are implemented. Programs should develop clear guidelines for making STGs operational at service delivery levels. Service providers and supply chain managers should sit on product selection committees to enhance the way in which they operate both the STGs and the design of ART programs.

**Key Consideration 7: ART program managers and product selection committees may need frequent updates to review ARV drugs on national essential medicines lists and to be in line with growing evidence and experience as treatment is expanded in multiple resource-poor countries**

Adding ARV drugs to NEMLs will greatly facilitate the implementation and enforcement of STGs and the ability of programs to monitor rational drug use.
and to effectively manage the supply chain for the drugs. In most countries, NEML revisions occur about every five years. In countries that do not already have ARV drugs on their NEML, an addendum specific to ARV drugs should be considered if a full review or revision is not possible. Given rapid changes in ARV drug technology and falling prices, five-year revisions may be too slow to keep pace with changing recommendations for ART. Clinical care committees may need to review and update the ARV drug portion of NEMLs on a more frequent basis—and in line with the growing body of experience coming from countries—as the committees expand treatment in resource-limited settings.

**Key Consideration 8: Policy makers planning updates to STGs and NEMLs for ART regimens should consider procurement lead times to ensure availability of ARV drugs at the time of implementation.** Programs generally have a three- to eight-month lead time for procuring ARV drugs. When program managers are planning to revise and update STGs and to make substantive changes in ARV drugs selected, planning should take into account procurement lead times so that formalization of a new STG policy can coincide with availability of the new drugs. For example, when moving away from the use of stavudine to zidovudine in first-line regimens, program managers should consult with procurement officers to determine the lead time for changing the drug supply before moving forward with plans to disseminate new STGs and to conduct training.
Key Consideration 9: Program managers must prepare medium-term forecasts to be able to coordinate funding and procurement among multiple donors and to ensure uninterrupted supplies of ARV drugs.

Developing countries currently lack the funds to procure sufficient antiretroviral (ARV) drugs to treat all clinically eligible people living with HIV/AIDS (PLWHAs). Furthermore, while national ARV programs are new and growing, few data are available to help with forecasting the demand for and use of ARV drugs. Preparing a medium-term forecast is a critical prerequisite for coordinating funding and procurement and will greatly assist programs in understanding their long-term needs, in assessing progress toward achieving treatment goals, and in setting new goals. Medium-term forecasts can be prepared using targeted numbers of patients identified for treatment in national strategies over a specific period of time and then combined with informed assumptions from key stakeholders and implementers. Those forecasts and procurement plans will need to be revised frequently as experience with acceptability, tolerability, and efficacy of ART is gained and as supply chain and services data are more available.

For the immediate term, quantification of needs for the first year can be conducted on the basis of available funding for a defined target population, on the existence of clear STGs, and on assumptions related to uptake, as well as using any available data on service statistics. Results from the quantification exercise should inform the first procurement cycle, although a logistics management information system (LMIS) should rapidly be implemented to collect supply chain data for future forecasts and procurement planning.

The assumptions about treatment and service use patterns that have been developed in conjunction with key informants for quantification should be updated as soon as services are available on a large scale. Key informants—the experts in clinical provision of adult and pediatric HIV care—should provide practical assumptions on service statistics and up-to-date information on approved dosages and prices.

To conduct the initial quantification, one needs for information needs to be available about the following:

- Standard treatment regimens recommended and approved for ART
- Local and international pricing information for all ARV drugs on the standard treatment regimens
- Estimated percentages of patients who will be initiated on first- and second-line drugs and on alternate first- and second-line drugs for both adults and children
- Estimated percentages of patients within each treatment regimen who will receive varying doses of ARV drugs according to weight band (adults and children)
children) and surface area measurements (children only)

- Estimated percentages of patients (adults and children) who will experience changes in treatment regimens because of these:
  1. Single drug substitution because of toxicity, drug interactions, or pregnancy
  2. Complete regimen switching because of treatment failure
  3. Discontinuation of ART resulting from dropout, death, nonadherence, or failure to follow up

- Estimated percentage of patients who are likely to receive specialized and short-duration regimens to address issues of tuberculosis and HIV co-infection and post-exposure prophylaxis.

**Key Consideration 10: Program managers should consult with experienced pediatric ART service providers when preparing forecasts for pediatric ARV drug needs so they can compensate for limited data and experience in this area of providing service.**

Quantification and forecasting for pediatrics where dosages of liquid formulations change as often as monthly is even more challenging and is an area in which additional data are urgently needed. A consultative process with ART stakeholders should be used to enhance accuracy and to ensure that the final quantities to order have been developed with input from a wide range of experienced national, regional, or international ART implementers. During initial forecasts, programs should estimate for higher wastage rates, especially for liquid formulations, given the complexities involved in changing dosages as those changes relate to weight bands.
A logistics management information system (LMIS) collects, processes, and reports supply chain data. A well-functioning LMIS provides decision makers throughout a supply chain with accurate, timely, and appropriate data (see box 3). The LMIS can be manual (paper-based), or partly or wholly computerized. For any supply chain system, the three essential LMIS data items are (a) quantity of stock on hand, (b) quantity of stock consumed (dispensed to users), and (c) losses and adjustments.

Box 3. The Need for Logistics Data to Inform ARV Drug Forecasts

A West African country preparing to implement a national antiretroviral therapy (ART) program procured enough antiretroviral (ARV) drugs to treat 2,000 adults for two years. The calculation of estimated ARV drug needs was not based on realistic service capacity or utilization data, but rather on the amount of funding available. Recent evidence suggests that the program may not have enough service sites or providers to enroll 2,000 patients in the ART program before the drugs expire. With no LMIS in place, tracking consumption patterns of the ARV drugs so that they can be distributed to high-volume sites will be difficult, and the risk of expiry or product mismanagement is high. Recognizing the potential negative impact for patients and the local and international publicity associated with wasting large quantities of these life-saving drugs, the program has prioritized the development of an LMIS. The system will assist with optimal management of existing ARV drug supply and with providing realistic trends in future consumption, which can be used for preparing the next forecast and procurement plan.

Key Consideration 11: To respond quickly and accurately to changes in demand, to supply the correct quantity of quality drugs, and to minimize pilferage and misuse of ARV drugs, the LMIS should be designed and implemented before the arrival of ARV drugs.

Close monitoring of the consumption and stock levels of ARV drugs is particularly important for supplying the correct quantity of quality drugs, for responding to changes in demand, for managing increased volumes of commodities, and for minimizing pilferage and misuse. A well-functioning LMIS can help ensure that those functions are fulfilled.

Lack of both resources and political support in most countries has prevented the implementation of an LMIS for most essential medicines. But because of the large influx of resources for the treatment, the expansion and the risks associated with interrupted supply of ARV drugs, and the intermittent provision of treatment,
implementation of an LMIS is considered a critical intervention when establishing ART programs. Although it is too early to know the costs of developing such systems, the issue of allocating financial resources for development and maintenance must be addressed. Without funding for this purpose, ARV drugs of the right type and in the right quantity will likely not reach the ART care sites and, ultimately, the people living with HIV/AIDS (PLWHA) on a regular and timely basis.

Ideally, the LMIS should be designed and be in place before the distribution of ARV drugs begins. Practically, this arrangement may not be feasible, especially given the focus on rapidly scaling up access to treatment. But development of an LMIS that is specifically for ARV drug tracking should be a priority intervention during the early stages of ART program implementation. In the short-term, the LMIS may need to begin as a parallel system; however, the cost-effectiveness of such an approach should be continually reassessed in the medium to long term, as more PLWHA receive treatment and as health system requirements and capacity change over time (box 4).

In addition to an LMIS, functioning systems for individual patient’s medical record keeping, reporting, and monitoring are critical for providing routine feedback from clinical and pharmacy records. This set of systems allows toxicity, resistance, dropouts, and stock status to be detected and reported regularly; it allows the forecast of needs to be adjusted and for the shipment quantities and product formulations to be changed as needed. Similarly, given highly mobile populations in many resource-limited settings, the ability to track ARV supply needs as patients move through the system is critical to maintaining as many patients on uninterrupted treatment as possible. Such a system must take into consideration issues of patient confidentiality so that inadvertent disclosure is not made.

When designing national LMIS, program managers should consider the costs and benefits of manual and partly computerized approaches to data collection and management. Examples of electronic methods of data capture include technological innovations such as bar coding, smart cards, and handheld devices.

**Box 4.**
**Implementing LMIS for ARV Drugs: The Experience in Uganda and Ghana**

The national ART programs in both Uganda and Ghana have chosen to implement vertical LMIS for ARV drugs. The LMIS’ have only one additional data item besides the three essential logistics data elements—quantities of drugs to order for estimated new ART patients. The programs have developed worksheets to assist providers in translating estimated numbers of new patients into quantities of drugs to order, and this translation has enabled facilities to maintain continuous supplies of ARV drugs while enrolling new patients on ART.

**Key Consideration 12:** Without compromising on the timeliness of supply chain data collection and use, program managers should identify strategies to cross-check patient and clinical data with
supply chain data so they can enhance clinical monitoring and accountability and can make informed forecasts about ARV drugs.

National ARV programs should identify minimum essential data elements required for both patient and drug monitoring and should develop both a strategy and implementation guidelines for routine data collection, reporting, and analysis so the programs can assist with ongoing clinical management and supply chain management. Managers responsible for monitoring data for patients and those responsible for monitoring supplies of ARV drugs at the program or site level should work together to identify common data elements and to develop methods in which data can be shared. For many public health programs, health management information systems (for service use data) and LMIS (for supply chain data) traditionally operate side by side as two separate, unlinked systems. In the case of ART, expanding the LMIS to include a limited amount of patient data—namely numbers of patients by regimen—would bring several benefits, including enhancing accountability of drug tracking, identifying irrational prescribing and dispensing patterns, monitoring toxicity and regimen changes, informing forecasting and the resupply of drugs, and integrating the adherence and program monitoring. As mentioned earlier, any data collection system that collects information about individual patients must have in place the necessary safeguards to protect patient confidentiality.

It will be important to decide whether to implement one integrated information system or to have two separate systems. In many countries, it has proven more effective to maintain a separate LMIS that provides timely operational data used for day-to-day decisions (e.g., for resupply). Burdening an LMIS with an excessive amount of patient, clinical, or program data will detract from the data’s effectiveness for supply chain management. However, at the central level, it would be useful to cross-check data from LMIS with that from health management information system (HMIS) for strategic and policy-related decisions and actions.

Steps in the development of an LMIS are as follows:

1. Determine the list of other data elements that must be collected in addition to the essential supply chain data to facilitate supply chain system functioning. Ensure that this information is coordinated with the data requirements for patient and program monitoring through a consultative process involving program managers and ART service providers. Also define the types of feedback and output reports required by users.

2. Decide on the scope of the information systems that will be implemented for collecting all data related to ARV drugs (i.e., patient, clinical, supply chain, financing, etc).

3. Explore cost, feasibility, and buy-in for different information system models: manual, semicomputerized, and fully automated or computerized. Include consideration of locally available technological innovations (e.g., bar coding, smart cards, palm pilots).

4. After the design of a system (including forms) has been determined, define procedures for information gathering, reporting, and analysis, and then document them in a procedures manual for each level of the distribution system and service site. Procedures should also be developed or refined for inventory management at all levels and should be aimed at ensuring minimum stock levels, as well as secure storage and distribution throughout the supply chain.

5. Begin system implementation by pilot testing it in sites already providing ART.
As part of system rollout, develop job aids to enhance the daily workload of health workers in using and maintaining the system.

6. Ensure that the final LMIS is owned by and closely linked with all other ministry of health systems (HMIS, etc).

When one considers implementing computerized systems, it is more efficient to start by computerizing supply chain information management at a central location and then by moving toward peripheral sites. Generally, central drug procurement and distribution centers are already computerized—although the degree of sophistication in computerization varies significantly; those centers have a better availability of hardware and more computer savvy personnel. If the centers are semiprivatized, they are likely to have lower staff turnover than in the public sector at regional or district levels.
Key Consideration 13: Program managers can maximize the funding that is available for purchasing ARV drugs by streamlining the pipeline, by monitoring inventory levels, and by securing transportation and storage facilities.

The value of antiretroviral (ARV) drugs in terms of cost, as well as life-saving potential, can create incentives for mismanagement and for pilferage if appropriate inventory control procedures and systems are not implemented. Furthermore, initially supplies of ARV drugs will be rationed, because countries do not have sufficient funding to treat all people living with HIV/AIDS (PLWHA) who need national antiretroviral therapy (ART). Therefore, in addition to careful forecasting, strict monitoring of inventory levels and secure transportation and storage facilities can play a key role in streamlining the supply and, thus, in maximizing the numbers of patients that programs can enroll for ART. New procedures for handling ARV drugs should be as consistent as possible with existing procedures for handling high-cost or classified drug items at hospitals or facilities. However, the unique nature of ARV drugs will, at times, require special consideration and procedures. As such, it may not be possible to fully integrate them into existing drug management systems.

Programs must plan for buffer stock at all levels, which will help prevent stockouts at the national level caused by delays in the release of funds or resulting from procurement problems. Stockouts can also occur at dispensing points as a result of uncertainties in patient uptake, different financing cycles, changes in patient treatment regimens, and transport reliability.

However, the cost of holding this inventory is a key consideration when designing the inventory control system and should take into account the infrastructure for storage and transportation. Maintaining high buffer stocks to guard against the problems identified earlier will ultimately result in fewer PLWHA being on treatment that is based on available resources. But too low or no buffer stocks will almost certainly result in prolonged stockouts of ARV drugs. One solution that many programs are implementing is to develop a vertical supply chain system for ARV drugs, one that eliminates some of the reasons for holding high buffer stocks but that still includes some buffer against uncertainty.

Programs can also design the distribution system to include as few levels as possible. A shorter pipeline will mean the following:

- Fewer points at which ARV drugs will be stored, thus decreasing the number of sites to be monitored and facilitating timely submission of reports and training of staff members in supply chain for ARV drugs
- Fewer locations at which security needs to be upgraded
- Streamlined transportation and reduced costs
- Reduced need for buffer stock of all drugs, thus maximizing the use of avail-
able resources
• Increased ability for central levels to respond rapidly to lower-level site requirements in the case of stockouts

Inventory Control Strategies

Most successful inventory control systems are maximum–minimum inventory systems or systems that ensure that the stock levels are maintained within an established range. Product managers routinely monitor consumption and stock balances at facilities to calculate new order quantities. The design of the system, including the selection of the standard review period for placing routine orders, is geared at ensuring the use of logistics data and lead times to make resupply decisions and thus to prevent stockouts.

Key Consideration 14: In new programs, program managers should consider a different inventory control mechanism for second-line ARV drugs as a way to reduce drug costs and opportunities for the mismanagement of ARV drugs.

ARV drugs used in first-line regimens are generally significantly less costly than those required for alternate or second-line regimens. Because many of the first-line regimens are available in generic, fixed-dose-combination formulations, those pills cost significantly less than second-line drugs and are easier to manage throughout the in-country supply chain. Particularly in the first few years that programs scale up, the drug requirements for first-line drugs will far exceed the quantities of drugs required for second-line regimens. Furthermore, site requirements for quantities of second-line regimens will be much more difficult to predict. Assuming that a population made up primarily of ART-naive users is receiving treatment through the public sector, the majority of patients will be on first-line drugs, and second-line regimens will not be required in large quantities during the first and second years. Substitution drugs for first-line treatment are intended for those patients who develop toxicity or side effects either for recommended first-line treatment or in the case of drug interactions. Although those drugs are slightly more costly and are not required in large quantities, a stock of the substitutions must be maintained at sites, because they will be required immediately to ensure that patients can substitute one drug and continue on ART rather than stopping all treatment unnecessarily. For second-line regimens, however, patients can wait a few weeks or months before they switch regimens, thereby allowing for some flexibility in regard to where drugs are stored.

To reduce the holding cost of second-line drugs and also to reduce the opportunities for pilferage or mismanagement of ARV drugs, supply chain managers should consider selecting a different inventory control mechanism for second-line regimens, compared to what may be used for first-line drugs (box 5).

Another mechanism is for the program to contract emergency distribution using courier services, which guarantee rapid distribution of ARV drugs from central storehouses to distribution points or facilities. Although those services are likely to be costly, such contracts will ensure timely and consistent deliveries and are still likely to cost less than maintaining higher buffer stocks of the drugs for alternative regimens at each site. Also, maintaining a central stock of the items will also mini-
Box 5. Adapting Inventory Control Mechanisms for Second Line ARV Drug Regimens

A number of sub-Saharan countries are currently centralizing storage of stocks for second-line regimens and sending them out to sites on an “as needed” basis, or they are asking lower-level sites to refer patients to other locations to receive the drugs. In one country, rather than assuming that every site will require second-line drugs and estimating an average quantity per site to distribute to each site, which is likely to be inaccurate, the program is maintaining stocks for second-line drug regimens at the central level because the national medical stores can reach any site in the country within 24 hours. To address the same issue and also to control storage conditions for second-line drugs, some of which require refrigeration, another country maintains buffer stocks at district levels.

To minimize the risks of loss through pilferage and expiration because it will facilitate the tracking of inventory levels.

Keeping the stocks at the central level can potentially help the ART program manager to better track information on regimen switching if the program managers are closely involved in authorizing the distribution of the drugs or if they receive timely information on quantities distributed. This information can then be rapidly fed back into updating forecasts, particularly until the LMIS is functioning well.

**Key Consideration 15: To minimize the risk of expired ARV drugs, programs should not accept drugs with less than the required shelf lives.**

The shelf life for most ARV drugs is between 18 and 36 months. To reduce the risk of expiration, procurement contracts for ARV drugs should specify a required minimum remaining shelf life on the drugs at the time that they arrive in country. National laws in many countries usually set this requirement at a minimum of either two years or 75 percent of total shelf life. Particularly during the initial expansion period when demand and uptake of ART is uncertain (especially at new sites), ARV drugs may not be dispensed as rapidly as expected. It is thus prudent not to accept drugs with less than the required shelf lives unless there is an emergency stock situation and the supply is guaranteed to be used.

Institutions responsible for the storage and distribution of ARV drugs should be selected or upgraded to ensure the following:

- Storage spaces that are secure
- Storage conditions that promote quality of commodities
- Ability to maintain frequency and mode of transportation that are based on the system design
- Clearly documented procedures for responding to requests from implementing sites and for obtaining data and authorization for conducting distribution
- Clear mechanisms for issuing invoices and receiving payment—if the system involves any type of cost recovery for commodities—or for issuing reimbursement for services rendered

The last item is particularly relevant in the cases of national medical stores, which
are operating as parastatal entities and are performing storage and distribution functions for the ministry of health.
Section VI

Procurement

Key Consideration 16: Policymakers and program managers should work closely with national drug regulatory authorities to ensure that lack of registration of ARV drugs is not a barrier to product availability.

New drug registration can be time-consuming, costly, and complicated. In many countries, the time between a new drug’s application and its registration can take anywhere from 3 to 24 months, largely because of delays in documentation and communication. The paperwork is intended to minimize the risk of having a substandard or counterfeit product enter the country; however, it often leads to an inefficient and burdensome process of registering products.

Drug registration is the responsibility of the manufacturers; until they are convinced that there will be a return on their investment, many manufacturers do not immediately register new drugs or new strengths of existing drugs. Because antiretroviral therapy (ART) programs are still new in many countries, not all of the commodities to support the program, including antiretroviral (ARV) drugs and specialized drugs for treating opportunistic infections (OIs) are likely to be registered at program inception. Furthermore, with more and more generic manufacturers producing ARV drugs, lack of registration could potentially be a significant barrier or cause of delays. This lack can significantly affect program planning for procurement and expansion. If procurement planning is conducted on the basis of accessing low-cost, high-quality drugs and yet those drugs are not yet registered in the country, the program risks stockouts and delays in implementation. Unregistered drugs will likely be stopped at the port, be held in customs, and eventually be returned to the shipper.

Access to ARV drugs can be expedited significantly in some countries by “fast-track” registration. In other countries, national drug regulatory authorities will issue waivers for special categories of drugs such as ARV drugs. Nonetheless, issues of registration are key considerations for ART program expansion and should be addressed early in program planning. Once procurement has been conducted, regular communication and coordination between the regulatory agencies and the procurement committee or agent are simple steps that can help minimize delays and facilitate access.

A balance needs to be struck between speed in the registration of all new products and thoroughness to ensure initial and ongoing quality control. The quality of imported or locally manufactured drugs should never be compromised through fast tracking or by issuing waivers. Nor should delays in registration become a vehicle for protecting local monopolies.

Furthermore, countries should strengthen procedures related to registration and importation of ARV drugs. Specifically, they should do the following:
1. Include consultation with the national regulatory authority—as part of the procurement evaluation and tender process procurement committee for ARV drugs—to minimize potential delays related to registration and importation.

2. Encourage companies that win tender awards to submit importation documentation several weeks before the product arrival at the port, to expedite the importation process (customs clearance), and to minimize delays.

3. Strengthen the capacity of the national regulatory authority for inspection, quality control, and registration, with an overall goal of reducing delays in registration and enhancing the availability of data on drug quality. Specifically, capacity is required for training and evaluation in inspection of ARV drugs.

Similar to considerations surrounding registration, national policies regarding the duty and tax status of ARV drugs should be reviewed to facilitate access and to maximize the use of resources to procure ARV drugs and to cover the costs of their distribution.

Key Consideration 17: Review tax and duty policies to ensure that there are no unnecessary barriers to availability of ARV drugs.

Taxes and duties on supplies, drugs, and equipment needed for HIV/AIDS services can create delays and blockages in the supply chain of those commodities, potentially leading to stockouts and irrational use of some commodities. Reducing or eliminating such barriers help ensure that all commodities will be distributed quickly and with minimal delay (box 6).

Key Consideration 18: To enhance the quality of ARV drugs and to minimize the risks of procuring counterfeit drugs, governments and partners should strengthen quality assurance and human resource capacity of national drug regulatory authorities and national quality control laboratories.

Countries have different quality assurance (QA) mechanisms and requirements for

Box 6.
Challenges Importing Donated HIV/AIDS Commodities

In one African country, the states are expected to pay for the taxes to cover the value of donated products. They do so in a paper transaction between the central and state governments. However, items are often stuck in the customs warehouse for long periods until the transaction is completed. In 1998, laboratory reagents for one region were wasted because no one could work out the process to complete the tax transfer. To make matters worse, the region was left holding the demurrage bill. An adequate central commodity system for would have flagged the tax issue for the donor organization and provided advance notice of the shipment to country managers, so that the tax transaction could be completed before products arrived and subsequently spoiled.
imported drugs. QA procedures should be in place throughout the supply chain. The appropriate procurement mechanism is important for ensuring product quality. For example, in its procurement guidelines, the World Bank recognizes that international competitive tendering, although healthy for promoting a competitive environment, can be deleterious to emerging HIV/AIDS programs that are in the process of rapid expansion (World Bank 2004).

Because the risk of counterfeiting ARV drugs is high, strengthening the capacity of national regulatory authorities to conduct appropriate QA tests and analyses is critical. Increased capacity includes expedited testing processes so that drugs are not held up extensively at ports; it also increases resources, skills, and equipment for commodity testing. A major area of weakness in many countries requiring enhancement is insufficient human and financial resources to conduct postmarket surveillance.

Given that an increasing number of countries are looking at local manufacture of ARV drugs, QA through postmarket surveillance will be a key function of regulatory authorities. Capacity in postmarket surveillance and evaluation of ARV quality should also be enhanced in preparation for ART expansion across the nation. Data collected for QA purposes should be consistent, regardless of whether it is gathered at the time of importation or through postmarket surveillance.

**Key Consideration 19: Consider standardizing procurement procedures or using alternative procurement methods that offer quality drugs at lower prices, such as international, regional, or other pooled procurement mechanisms.**

Standardizing procurement approaches and using pooled or central procurement mechanisms are critical strategies for ensuring the purchase of quality drugs. Many countries are facing an environment with multiple procurement agents buying ARV drugs, which may be associated with requirements of different funding sources. For example, a single country could have ARV drugs purchased by the following:

- The government's procurement office or agency, such as the central medical stores
- The local project office of the World Bank's Multicountry AIDS Program
- The local agent appointed by the Global Fund to Fight AIDS, Tuberculosis, and Malaria
- One or several procurement agents purchasing ARV drugs for the nongovernmental organization (NGO), mission, private voluntary organization (PVO), and faith-based organization (FBO) communities and facilities
- The local or international agent for the U.S. President's Emergency AIDS Plan

Guidelines and a decision on aligning procurement procedures and ensuring pooled, centralized, or coordinated procurement by several donors for ARV drugs will ensure that funding is used effectively, that ARV drugs arrive regularly, and that duplication of orders and wastage is minimized. Pooling procurement helps exploit economies of scale—both through bulk purchase and by reducing duplicative activities—such as QA—offering large cost savings to cash-strapped programs.
The United Nations Population Fund (UNFPA), United Nations Children’s Fund (UNICEF), and Global Facility for Tuberculosis are all examples of pooled procurement on an international scale. The Global Fund offers an information-sharing database in which recipients can share their information about commodity costs (visit http://www.who.int/3by5/amds/price/hdd/). Where a single procurement agent is not feasible, primary procedures should be standardized, such as product specifications for ARV drugs.

**Key Considerations 20:** Program managers should ensure that procurement contracts are flexible and should allow for multiple shipments and modifications of order quantities to respond to uncertainties and fluctuations in demand during initial program expansion.

Guidelines on procurement should balance the need for QA mechanisms with those that allow flexibility within existing contracts and for future contracts. Existing contracts should be written to be flexible and responsive to fluctuations in demand and uptake of commodities through the ART program, especially as the program is growing. Also, given significant and ongoing reductions in prices, as well as rapidly emerging technology related to fixed-dose combinations, new drugs should have fewer side effects and new, user-friendly formulations should have procurement guidelines that allow countries and programs to benefit from the advances in technology and price reductions. As an example, a contract that locks a program into purchasing single drug formulations for second-line treatment at a specified price for two or three years may prevent the program from procuring a fixed-dose combination of the second-line treatment at a much lower price in year two or three.

**Key Considerations 21:** Program managers should develop a medium- to long-term procurement plan to coordinate drug inputs among donors, to identify clear resource mobilization needs, and to leverage competitive strengths in drug purchases.

In addition to the consideration of quality and price, a necessary step in the procurement planning process is to reduce the risks of stockouts and overstocks and to cater to new donors and procurement agents that are likely to emerge over time. Thus, at the national level, there needs to be a mechanism to coordinate funding, procurement, and shipments from multiple donors and sources, as well as to align available resources with estimated needs.

As mentioned earlier, a medium-term forecast can greatly assist with coordination. Once the forecast has been prepared, it can then be used to develop a medium- to long-term procurement plan and to coordinate procurements among various donors and sources of drugs. One advantage of this approach is that the ministry of health and implementing partners can be proactive about advocating for resource mobilization, because they have a clear estimate of costs for treating more patients. Furthermore, if new donors come on board during program expansion, the ministry has clearly defined the estimates of needs and the timeframe for when commodities are required. It can also direct new donors toward investing in gaps rather than risking duplication of investment.

Yet another benefit is that different donors can leverage their relative strengths
when making procurement decisions. For example, governments that have limited funds can invest their resources in the purchase of low-cost, prequalified generic ARV drugs and can leave the purchase of originator products to donor partners. Donors such as the U.S. President's Emergency Plan for AIDS Relief can purchase second-line regimens, most of which are available only in branded form and need to be purchased from originator manufacturers anyway.

Another consideration is aligning procurement for ARV drugs with the procurement policy for all other essential medicines. It is important that procurement procedures for all items are standardized and consistent with health sector goals for improving the overall performance of the health system. In several countries where procurement arrangements are not standardized, transparent, or efficient, donor projects generally make their own individual and diverse procurement arrangements, and this practice often results in supply imbalances, in gaps in information on quantities procured, in money spent, and in weakness in the ultimate performance of those arrangements.

In the long run, resources should be invested in strengthening the local procurement capacity. Initially, for effectiveness and speed, the donor-appointed procurement agents or the centralized and pooled mechanisms are often the obvious choice for procurement. However, over time, transferring and building procurement capacity at the local level is a key element in improving the performance of the health system. Investment by governments and partners in more efficient, accountable, and transparent processes and systems will be critical to the success of long-term and improved procurement capacity at the local level.
Section VII

Financing

The high cost of antiretroviral (ARV) drugs remains a significant barrier to expanding access to antiretroviral therapy (ART) in many resource-limited countries. Costs for ARV drugs vary significantly depending on whether they are branded or generic. Although branded drugs are generally more expensive, sometimes they are not. In the interest of enhancing access over the long term, ART programs should consider procurement of ARV drugs with the lowest cost, as long as drug quality is ensured.

Another key consideration that countries and programs must address is the long-term financing strategy for the ART program, specifically for ARV drugs. An ongoing debate relates to whether ARV drugs should be provided completely free, thus enhancing the likelihood of adherence and promoting equitable access, or if a combination of cost-sharing, cost-recovery, and insurance schemes should be implemented to provide sustainable sources of financing for purchasing ARV drugs.

Key Consideration 22: Program managers should implement consistent policies and guidelines related to free versus subsidized ARV drugs in the public sector, keeping in mind the need for long-term financing of ARV drugs and the effect of pricing policies on the implementation of the supply chain.

Financing and ability to pay are issues that greatly affect the demand for ARV drugs and the distribution of the products. Programs should develop and implement a consistent policy and guidelines regarding payment or nonpayment for ARV drugs.

At the national level, the policy should address how purchase of ARV drugs and maintenance of the ART program will be financed in the long term and should include a variety of financing strategies to achieve the policies. The policy should balance financial requirements against other goals, including those for enhancing equitable access, especially for the poor, and for ensuring that implementation of an ART program does not distort budgetary allocation away from other health priorities, such as primary care and basic HIV care. This priority setting is especially important in highly decentralized settings where districts and subdistricts make their own financial allocation decisions. Finally, the policy should have a component on pricing in the public, private, and civil society sectors and should ensure that the policy is consistent with the achievement of program goals. One example is to develop policies to safeguard against those who can pay for accessing highly subsidized drugs at the expense of those who cannot pay.

To put the policy into operation, one should make sure that the guidelines include clear criteria to assist and guide health workers in implementing cost sharing, cost recovery, insurance schemes and subsidies, waivers, and exemptions. From a supply chain perspective, it is important to anticipate the effect of develop-
Key Consideration 23: Policymakers and donors should ensure that supply chain management costs such as storage, distribution, and LMIS are covered so product availability to patients is not interrupted

In addition to funding for procuring ARV drugs, costs for managing, storing, and distributing the commodities need to be budgeted for and financed. Central drug agencies that handle procurement commonly include a percentage mark-up on the value of the drugs, and this mark-up covers costs of procurement services, shipments, contract monitoring, customs clearance, and taxes, among other things. For supply chain management, it is necessary to make sure that system development and maintenance costs are included in budgets. Those costs include, but are not limited to, storage, handling, stock-level monitoring, data collection, submission and analysis, and distribution costs.

If supply chain management costs will be handled through a mark-up associated with the value of the incoming drug shipment (as some countries do with other essential medicines), the value of the mark-up must be carefully negotiated, given the changing prices of ARV drugs. In the case of high-value items such as ARV
drugs, it may be that the percentage mark-up can be lower than for other drugs and still cover management and distribution costs incurred. Important to keep in mind are the significant price reductions for ARV drugs that have occurred over a very brief time period, mainly as a result of competition from generic drugs. Thus, price negotiations based on value should take into account possible devaluation in the price of ARV drugs over time. The price negotiation should also take into account extra measures for ensuring security, quality assurance, and regularity of the supply.

In many countries, the storage and distribution functions for the national program are outsourced to the central medical stores, to similar parastatal entities, or even to private providers of warehousing and transportation services. In such cases, budgeting involves two parties and will require clear relationships among the ministry of health, the national program, and the organization providing storage and distribution services. Arrangements should be made to ensure that timely payments are made so that those functions are ongoing.

A supply chain cost that has not been addressed for most other categories of essential medicines is the cost of developing and maintaining a logistics management information system (LMIS). For ARV drugs, a well-functioning LMIS is the key to ensuring an uninterrupted and secure supply of drugs. Funding for LMIS implementation and maintenance is crucial to include. Because this function is usually conducted as part of the ministry of health’s ongoing operations, it may not be a separate budget item, although it is critical that those costs are budgeted for so that they are able to be performed. For a manual system, costs to budget include personnel time for data collection, aggregation, analysis and management; costs of printing and distributing forms; and costs for sending and receiving data. Costs for a computerized system will obviously include those for a manual system, as well as the costs for computerization or for other automation expenses. Finally, training and supervision must be budgeted for so one can ensure effective implementation and maintenance.

**Key Consideration 24: Program managers should take advantage of offers of donations of ARV drugs, while ensuring that clear and comprehensive guidelines for accepting drug donations address the characteristics of ARV drugs and the costs associated with managing donated items.**

Product manufacturers have already established HIV/AIDS commodity donation programs. Abbott Laboratories donates Determine HIV test kits, and Boehringer Ingelheim donates nevirapine for the prevention of mother-to-child transmission (PMTCT) programs. Pfizer donates Diflucan (fluconazole) to countries to treat opportunistic infections. Those donation programs often have burdensome and separate reporting requirements that may not be useful for commodity management. Nonetheless, reports should include accountability of how commodities have been used, which can easily be extracted from an LMIS. By submitting timely information from the LMIS, managers can support the uninterrupted supply of the commodities.

Donated items, because of their time-limited nature and special reporting requirements, tend to be more expensive to manage in the supply chain system. Given scarce resources, there will, nonetheless, be ARV drugs donated for specific purposes or projects. In such cases, programs must make key policy decisions and
develop implementation guidelines to clarify the management of donated items. Key issues include the following: Will donated ARVV drugs be subject to the same policies as public sector procured ARV drugs? Are there clear policies for dealing with donated drugs? Will donated ARV drugs follow the procedures that have been developed for all other donated drugs?

Issues to consider regarding donated ARV drugs include (a) quality assurance, (b) consistency of drugs and packaging with recommended standard treatment regimes for the public sector, (c) finances for any supply chain costs, and (d) any potential costs of those donated drugs to patients. If donated drugs arrive in large amounts for specific geographic regions or sites, this volume could potentially disrupt existing trends in consumption and distribution through the normal supply channels, which should be taken into account when developing procedures for supply chain management of those items.
An enabling policy environment must exist for supply chain systems to operate effectively. Because many policies are being developed while programs are expanding, policymaking bodies should consider developing policies that will be valid throughout the antiretroviral therapy (ART) scale-up process. Policies should be complemented by comprehensive implementation guidelines that will be continuously updated as programs evolve and as national-level experience related to financing, forecasting, procuring, and distributing emerges. This section presents key considerations for policies addressing the broader health, social, and legal issues affecting supply chain management.

**Key Consideration 25: To provide safe, effective, and comprehensive ART services, program managers must purchase and implement effective supply chains for 100 to 200 other commodities in addition to ARV drugs.**

Although antiretroviral (ARV) drugs are one of the most expensive commodities in HIV/AIDS programs, they are only one of the approximately 100 to 200 commodities required to support the provision of comprehensive HIV/AIDS prevention, care, support, and treatment. Availability of certain of those other items is critical to effective ART provision. Without HIV test kits, for example, clients cannot learn their HIV status and make decisions about ART initiation. Frequently, opportunistic infection (OI) drugs must be taken concurrently with ARV drugs, and sometimes lab tests may be required before service providers can switch patients from one ARV regimen to another. Thus, supply chains must exist and function effectively for all the other commodities, not just for ARV drugs. Thus, funds must be allocated for the purchase of those commodities and for maintaining their supply chains. Although this paper will not focus on any of the other commodities, the majority of supply chain considerations described for ARV drugs apply to the other commodities that are required for effective HIV/AIDS program implementation.

**Key Consideration 26: Without a body to oversee, coordinate, and track resources that have been promised and allocated, identifying gaps in funding, drug supply, and technical assistance could be a significant barrier to ART scale-up.**

Coordinating the financing and procurement of ARV drugs from an increasing number of partners is a perpetual challenge that many national programs are facing. Specific details of what needs to be coordinated are discussed in the procurement section. An important issue that policymakers must address, however, is identifying which organization at the national level will be responsible for coordinating the funding and procurement of ARV drugs. The mandate of the organization will be to coordinate and advocate for specific financial and procurement resources to
meet the identified requirements from the forecast, as well as changing needs as the program evolves. As an example, there are often multiple recipients for ARV drug funding in a given country.

The World Bank’s Multicountry AIDS Program will often work outside the ministry of health with the multisectoral national AIDS commission, which is located in the president or prime minister's office. The Global Fund to Fight AIDS, Tuberculosis, and Malaria often identifies the ministry of finance as its principal recipient. U.S. government funds or financing from other bilateral agencies will often be channeled through the ministry of health. Without a body to oversee; to coordinate; and to track amounts of money promised, time periods of commitment, and actual release of funds, then identifying gaps in funding will not be easy or systematic. Furthermore, advocating for more resources and conducting procurement planning to ensure an uninterrupted supply at the national level will be even more challenging. Ultimately, the lack of coordination is likely to lead to supply imbalances, stockouts, and wasted resources.

In the long run, tracking the various inputs will also allow the national program to plan for funding of ARV drugs past the first two or three years for which it has funding commitments. To date, few funding organizations have committed funds for any national program during the past three years. Tracking incoming funds for drug and other commodity purchases, such as for HIV/AIDS and ART programs scale-up, will facilitate planning for procurement and resource mobilization in the case of funding shortfalls.

**Key Consideration 27: Policymakers and program managers should involve politicians and communities early in planning the ART program to promote ownership, to share responsibility for access decisions with people living with HIV/AIDS, and to manage expectations around national goals.**

Involving people living with HIV/AIDS (PLWHA), other community members, and the politicians in the decision-making process and developing communication strategies to target those groups will be critical to the success of an ART program. In countries most affected by the HIV/AIDS pandemic, politicians are under increasing pressure to demonstrate their commitment to addressing HIV/AIDS as a national issue. Involving politicians during early policy development can be useful in addressing issues of stigma and discrimination, which can be a significant barrier to ART uptake and ultimately can affect the status of ARV drugs in the supply chain. Poor uptake could result in overstocks and wastage. Furthermore, if politicians participate in and are educated and informed about the national strategy and components in the operational plan, there is less likelihood that they will enact ad hoc policies under pressure. Instead, they will respond in ways that are consistent with existing policies and decisions.

Communities play a critical role in a successful ART program across the nation. Because the incoming supply of ARV drugs will still not be sufficient to treat all clinically eligible PLWHAs, the community can be involved in developing social criteria at the local level for ART eligibility and enrollment. This involvement is likely to assist in managing expectations and in reducing resentment between the haves and have nots and the community and service providers at facilities. Community involvement can also be critical in promoting adherence, in educating patients
in the proper use of drugs, and in ensuring that facilities are transparent and accountable for implementing quality ART services. The most effective solutions for many issues with which programs are still grappling may, in fact, come from the community.

**Key Consideration 28:** When defining access criteria and referral mechanisms for ART, policymakers and program managers should consider implications for supply chain management and patient tracking.

In many countries, how patients will receive drugs when they move from one region to another is a significant challenge that ART programs have not yet addressed. Programs will need to define the mechanism by which patients may be able to change their resupply or dispensing point when relocating within the country. This mechanism is especially important if the supply of ARV drugs is rationed by geographic region, with each site or region receiving an allocated cap of numbers of patients who can be enrolled in ART. Resupplying ARV drugs to mobile patients will require a well-functioning referral system, an agile supply chain, and a set of clearly defined eligibility criteria for ART enrollment through the public sector. The national program does not have the ability to monitor each patient in the country, especially in countries with weak or nonexistent national identification systems. However, they can provide general guidelines to ensure that ART provision is consistent with national goals and strategies. For actual patient tracking, the community, together with facilities, is more likely than the national program to develop long-term workable solutions.

**Key Consideration 29:** To enhance the regulation of drug quality in the private sector and the sharing of patient and supply chain data, program managers should explore mechanisms to accredit public and private sector pharmacies to stock and dispense ARV drugs.

Countries and national programs are acknowledging that widespread ART coverage cannot be achieved without meaningful and healthy public–private partnerships. Past models of public–private collaboration offer some useful lessons but have significant shortcomings that must be addressed before they can be fully applied to ART. For example, experience from national tuberculosis control programs has demonstrated that sharing information and regulating drug quality and management in the private sector are difficult. Obtaining the information on numbers of patients treated, a profile of drugs prescribed and used, and the patient continuation and adherence rates from the private sector has also been a challenge for national public sector programs. Nonetheless, it is evident that many countries will not be able to rapidly expand ART services without a thoughtful and meaningful partnership with civil society and the private sector.

From a supply chain point of view, policies or guidelines for establishing and maintaining a fruitful partnership should be developed to address issues of quality and supply management. Many countries are exploring accreditation or certification strategies as a means of ensuring quality across all sectors while they address shortcomings from previous partnership models. As an example, for ARV drugs, a robust drug regulatory authority can be involved in accrediting both public and private sector pharmacies to stock and dispense ARV drugs, thus providing
oversight of the quality and source of the drug supply in the private sector. Criteria for accreditation can support monitoring program objectives and outcomes, such as reporting about basic supply chain and patient data. Incentives to enhance private sector participation should be carefully considered to ensure achievement of national goals that will provide effective low-cost antiretroviral treatment. For example, once the secure supply of high-quality drugs is ensured through the public sector, a benefit of the partnership is that private providers could gain access to competitively priced drugs for their patients. As another example, professional organizations can play a significant role in developing the criteria and in ongoing recertification or reaccreditation to ensure that standards are maintained over time.

**Key Consideration 30: Policymakers, program managers, and donors should balance short-term results and effectiveness with long-term system building so they can ensure the security of ARV drugs in the medium to long term.**

The need to strike a balance between long-term system building and short-term effectiveness and results remains and will still affect long-term success of HIV/AIDS programs. To ensure that the program is still able to ensure secure, uninterrupted supplies of ARV drugs and other HIV commodities in 5 to 10 years, one should view short-term solutions as temporary. In addition, program managers and donors should dedicate efforts toward improving those systems to be more robust and cost-effective in the long term.
Section IX

Conclusion

The 30 key considerations outlined in this paper are intended to assist policymakers and program managers to effectively implement and scale up national antiretroviral therapy (ART) programs. Those considerations span key legal, financial, clinical, supply chain, and human capacity-building activities, which play a critical role in ensuring a continuous supply of antiretroviral (ARV) drugs to clients. To focus on one aspect to the detriment of others will imperil the success of ART programs and will elevate the risk of widespread drug resistance.

The challenges highlighted in the paper are not negligible; successful adoption and implementation of policies, guidelines, and approaches will depend on the political will and commitment of a variety of stakeholders and decision makers at many levels. Once engaged, decision makers will face difficult decisions about access and must balance competing interests and influences. This paper presents solutions and approaches that are available for strengthening supply chains, that are feasible to implement, and that will improve the outcome of ART programs.
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Supply Chain Management of Antiretroviral Drugs


for International Development.


World Health Organization (WHO). 2003 (Revision). *Scaling Up Antiretroviral Therapy in Resource-Limited Settings: Treatment Guidelines for a Public Health Ap-

HIV/AIDS SERVICE DELIVERY PROGRAMS:
OVERVIEW AND INSIGHTS FOR SUPPLY CHAIN MANAGERS

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DELIVER

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Implemented by John Snow, Inc. (JSI), (contract no. HRN-C-00-00-00010-00) and subcontractors (Manoff Group, Program for Appropriate Technology in Health [PATH], and Social Sectors Development Strategies, Inc.), DELIVER strengthens the supply chains of health and family planning programs in developing countries to ensure the availability of critical health products for customers. DELIVER also provides technical management of USAID’s central contraceptive management information system.

Recommended Citation


Abstract

Delivering effective and quality HIV/AIDS services requires a comprehensive national HIV/AIDS program that ensures a functional and efficient supply chain for the commodities needed by each service delivery component. In order to create programs that can ensure the uninterrupted availability of product, logistics advisors should be aware of difficulties facing HIV/AIDS service delivery in resource limited settings. The document aims to improve the logistician’s understanding of the essential elements of a comprehensive HIV/AIDS program and how the different components relate to each other; how changes in services in each component can affect demand, uptake, or services in another and the need for products in each; and how, where and when different services are provided and managed within the health system.
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<thead>
<tr>
<th>ACRONYMS</th>
<th>Definition</th>
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<tbody>
<tr>
<td>ABC</td>
<td>abstinence, be faithful, correct and consistent condom use</td>
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<tr>
<td>ABC</td>
<td>abacavir</td>
</tr>
<tr>
<td>AIDS</td>
<td>acquired immunodeficiency syndrome</td>
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<tr>
<td>ANC</td>
<td>antenatal care</td>
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<tr>
<td>ART</td>
<td>antiretroviral therapy</td>
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<tr>
<td>ARV</td>
<td>antiretroviral drugs</td>
</tr>
<tr>
<td>BCC</td>
<td>behavior change communication</td>
</tr>
<tr>
<td>BCG</td>
<td>Bacillus Calmette-Guerin (vaccine for tuberculosis)</td>
</tr>
<tr>
<td>CDC</td>
<td>Center for Disease Control and Prevention</td>
</tr>
<tr>
<td>CHCT</td>
<td>couple HIV counseling and testing</td>
</tr>
<tr>
<td>DBS</td>
<td>dried blood spot</td>
</tr>
<tr>
<td>DOT</td>
<td>directly observed treatment</td>
</tr>
<tr>
<td>ECR</td>
<td>Expanded and Comprehensive Response</td>
</tr>
<tr>
<td>ELISA</td>
<td>enzyme-linked immunosorbent assay</td>
</tr>
<tr>
<td>FDC</td>
<td>fixed-dose combination</td>
</tr>
<tr>
<td>FHI</td>
<td>Family Health International</td>
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<tr>
<td>GDP</td>
<td>gross domestic product</td>
</tr>
<tr>
<td>HAART</td>
<td>highly active anti-retroviral therapy</td>
</tr>
<tr>
<td>HBC</td>
<td>home based care</td>
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<tr>
<td>HCW</td>
<td>health care worker</td>
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<tr>
<td>HIV</td>
<td>human immunodeficiency virus</td>
</tr>
<tr>
<td>IDU</td>
<td>intravenous drug use</td>
</tr>
<tr>
<td>JSI</td>
<td>John Snow, Inc.</td>
</tr>
<tr>
<td>KS</td>
<td>Kaposi’s sarcoma (cancer)</td>
</tr>
<tr>
<td>MSM</td>
<td>men who have sex with men</td>
</tr>
<tr>
<td>MTC</td>
<td>mother-to-child transmission</td>
</tr>
<tr>
<td>NGO</td>
<td>nongovernmental organization</td>
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<tr>
<td>NRTI</td>
<td>nucleoside reverse transcriptase inhibitor</td>
</tr>
<tr>
<td>NNRTI</td>
<td>non-nucleoside reverse transcriptase inhibitor</td>
</tr>
<tr>
<td>OI</td>
<td>opportunistic infection</td>
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<tr>
<td>OVC</td>
<td>orphans and vulnerable children</td>
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<tr>
<td>PCP</td>
<td>pneumocystis carinii pneumonia</td>
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<tr>
<td>PCR</td>
<td>polymerase chain reaction</td>
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<tr>
<td>PEP</td>
<td>post-exposure prophylaxis</td>
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<tr>
<td>PEPFAR</td>
<td>President’s Emergency Plan for AIDS Relief</td>
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<tr>
<td>PI</td>
<td>protease inhibitors</td>
</tr>
<tr>
<td>Acronym</td>
<td>Description</td>
</tr>
<tr>
<td>---------</td>
<td>-------------</td>
</tr>
<tr>
<td>PLWHA</td>
<td>people living with HIV/AIDS</td>
</tr>
<tr>
<td>PMTCT</td>
<td>prevention of mother-to-child transmission</td>
</tr>
<tr>
<td>RNA</td>
<td>ribonucleic acid</td>
</tr>
<tr>
<td>STI</td>
<td>sexually transmitted infection</td>
</tr>
<tr>
<td>STD</td>
<td>sexually transmitted disease</td>
</tr>
<tr>
<td>TB</td>
<td>tuberculosis</td>
</tr>
<tr>
<td>TLC</td>
<td>total lymphocyte count</td>
</tr>
<tr>
<td>TT</td>
<td>tetanus toxoid</td>
</tr>
<tr>
<td>UNAIDS</td>
<td>Joint United Nations Program on AIDS</td>
</tr>
<tr>
<td>UNICEF</td>
<td>United Nations Children's Fund</td>
</tr>
<tr>
<td>USAID</td>
<td>United States Agency for International Development</td>
</tr>
<tr>
<td>VCT</td>
<td>voluntary counseling and testing</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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</table>
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/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/AIDS services. The publication is also dedicated to friends and counterparts who have worked with DELIVER, 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/AIDS and laboratory commodities, we recognize that comprehensive HIV/AIDS and laboratory programs require the supply chain to manage and deliver a broad range of several hundred public health commodities.

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Public health service delivery encompasses activities implemented using service delivery models tailored to local, regional, and national policy and program contexts and needs. The process of designing, implementing, and evaluating service delivery includes a cycle of assessment, implementation, revision of the design, and further monitoring and evaluation.

In the case of HIV/AIDS programs, the process takes into account specific factors related to the epidemic in a country. In addition, program success is influenced by factors such as provider attitudes toward people living with HIV/AIDS and the accessibility, affordability, and acceptability of prevention, care, and treatment services.

Government ministries and donors at the national level are challenged to support service delivery at the facility and community levels. This support entails policies, strategies and guidelines, monitoring and evaluation plans, and approaches to build human capacity to deliver services that are supported by a secure supply chain for program drugs and commodities.

Service delivery is not possible without a comprehensive national HIV/AIDS program that ensures a functional and efficient supply chain for the drugs, supplies, and commodities needed by each service delivery component. The commodities range from condoms and test kits to drugs for pain management. It is critical that there be a coordinated program across levels of the public health care system including primary health care clinics, community health centers, district hospitals, and regional and tertiary health institutions.

It is also critical that supply chain personnel working in HIV/AIDS programs, as well as those who supervise them, understand the natural history of HIV disease, its effect on individuals and communities and the demands that challenge service delivery and national programs. This document is designed to provide logistics advisors with specific background information on HIV/AIDS and service delivery in resource limited settings, but it is not intended to provide a comprehensive overview of HIV/AIDS programs and services. Rather, this document focuses on those elements that will assist advisors in providing a foundation for understanding the context in which supply chains must be developed—from design through implementation and monitoring. Thus, supply chains can be agile and can respond to the requirements of rapidly expanding HIV/AIDS programs and, ultimately, can ensure uninterrupted product availability.

The document aims to improve the logistician’s understanding of the following areas:

- What the essential elements of a comprehensive HIV/AIDS program are, and how the different components relate to each other
- How changes in services in each component can affect demand, uptake, or services in another, and what the need is for products in each
- How, where, and when different services are provided and managed within the health system

This document draws from a variety of resources, including JSI’s domestic and international experience in HIV/AIDS service delivery and clinical care, as well as from a compilation of best practices and lessons learned from a variety of organizations that are working in HIV/AIDS program support and service delivery. Other references that provide more detail include the World Health Organization’s (WHO’s) Scaling Up Antiretroviral Therapy in Resource-Limited Settings: Treatment Guidelines for a Public Health Approach, plus Family Health International’s Strategies for an Expanded and Comprehensive Response (ECR) to a National HIV/AIDS
I. BACKGROUND

HIV/AIDS is a complex infectious disease that is now at the pandemic stage. While it is not possible to provide a thorough understanding of the disease in a brief document, some basic facts about HIV/AIDS that are critical to understand if one is to support programs for people living with HIV/AIDS. The following overview focuses on the basic facts logistics advisors and managers should be familiar with if they are to assist programs in acquiring and developing supply chains that will manage the HIV/AIDS commodities.

A. OVERVIEW: THE HIV/AIDS EPIDEMIC

As of 2005, 40.3 million people worldwide were living with HIV, up from an estimated 37.5 million in 2003. More than 3.0 million people died of AIDS-related illnesses in 2005; of those, more than 500,000 were children. According to the most recent reports, the steepest increases in HIV infections have occurred in Eastern Europe and Central Asia (25 percent increase to 1.6 million) and East Asia. But sub-Saharan Africa continues to be the most affected globally—with 64 percent of new infections occurring there, or more than 3.0 million people (UNAIDS, AIDS Epidemic Update 2005).

According to UNAIDS, more than 1.0 million people in low- and middle-income countries are now living longer and better lives because they are on antiretroviral treatment (ART). An estimated 250,000 to 350,000 deaths were averted this year because of expanded access to HIV treatment. Commenting on the potential enhanced effect of integrating prevention and treatment, the 2005 report emphasizes that a comprehensive response to HIV and AIDS requires the simultaneous acceleration of treatment and prevention efforts with the ultimate goal of universal access to prevention, treatment, and care.

The words HIV and AIDS can be confusing because both terms describe the same disease. It is useful to think of AIDS as advanced or severe HIV disease. A person with AIDS has an immune system so weakened by HIV that the person usually becomes sick from one of several opportunistic infections or cancers such as these illnesses: PCP (a type of pneumonia), KS (Kaposi’s sarcoma), wasting syndrome (involuntary weight loss), memory impairment, or tuberculosis. If someone with HIV is diagnosed with one of the opportunistic infections (even if the CD4 count is above 200), he or she is said to have AIDS. AIDS usually takes time to develop from the period in which a person first acquires HIV—usually between 2 to 10 years or more. After the person has been diagnosed with AIDS, she or he is always considered to have AIDS, even if that person’s CD4 count goes up again, if he or she should recover from the disease that defined the AIDS diagnosis, or both.

Drugs exist to prevent or treat opportunistic infections, but only antiretroviral (ARV) drugs will decrease the viral load, thereby allowing the immune system to rebound. Once started, a person with HIV/AIDS needs the drugs for the rest of his or her life.

The goals of a comprehensive program for HIV/AIDS in a country include reducing HIV transmission, reducing AIDS morbidity and mortality, improving the quality of life for people living with HIV/AIDS (PLWHA), and lessening the impact of the epidemic in affected locations and populations.

First, although this document and this section, in particular, focus primarily on the health sector’s response to HIV/AIDS, it is important to recognize that HIV is not only a health sector problem but also a multisectoral problem requiring a population approach rather than an individual approach to promoting good health.
Second, the social environment has been acknowledged to have a significant effect on individual and population health status.

**B. HIV/AIDS SERVICE DELIVERY**

The components of a comprehensive HIV/AIDS service delivery system should address needs along a continuum of care. That continuum ranges from supplying community education for risk reduction through care and treatment, to providing psychological and physical comfort to people who are dying of AIDS, and to mitigating the effect of the epidemic in a community. Services are designed for a country and then adapted to specific geographic locales as policy makers take into account the stage of the epidemic, the available resources, and the community preferences.

In general, people with HIV infection need comprehensive services along a continuum from the point of infection through testing, treatment, and palliative care. The services that they need change over the course of their illness. A component of a comprehensive continuum of care that meets the needs of community members—from the time they want to know their HIV status through a period of terminal illness—includes the following components:

- Behavior change communications (ABC, and so on) and condom social marketing for prevention
- Voluntary HIV/AIDS counseling and testing services—provider- and client-initiated
- Prevention of mother-to-child transmission
- Post-exposure prophylaxis
- Psychosocial support
- Clinical care and treatment, including the prevention and management of opportunistic infections, symptom management, and antiretroviral therapy
- Nutritional assistance
- Community-based services
- Home-based care

A comprehensive national HIV/AIDS program supports the delivery of those components of care through the following program components (FHI, The Expanded and Comprehensive Response 2005):

- Strategic planning
- Technical strategies
- Administration and resource management
- Nongovernmental organization (NGO) involvement
- Human capacity development
- Costing and use of resources
- Managing the supply chain for commodities
- Measuring for impact
The components of a comprehensive program range from those interventions directed at the primary prevention of HIV, to those aimed at providing psychological and physical comfort for people who are dying of AIDS and at mitigating the impact of the epidemic in a community. The interventions are based on the needs of members of the community at different times in their lives, such as when they are not infected but want to know their status or when they are infected and need care and treatment. Figure 1 illustrates the services needed for various members of a community.

**Figure 1. Standard Care Services for HIV/AIDS**

<table>
<thead>
<tr>
<th>Services</th>
<th>Uninfected People</th>
<th>Exposed People</th>
<th>People Living with HIV</th>
<th>People Living with AIDS</th>
<th>Terminally Ill and Beyond</th>
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<tr>
<td>Prevention of Mother-to-Child Transmission</td>
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<td>Psycho-Social and Spiritual Support</td>
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<td>Individual and Family</td>
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<td>Care Providers</td>
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<td>Orphans</td>
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</tr>
<tr>
<td>STI Services, Behavior Change Communication, Education, Universal Precautions</td>
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</table>

HIV/AIDS programs depend on continuous supplies of commodities, which is achieved through well-functioning supply chains that ensure those supplies are available where and when needed. Services require care that is supported by community outreach and education, adequate laboratory infrastructure, and effective supply chain management. Clients need education and outreach to contemplate and accept HIV counseling and testing, which also must be in place. A counseling and testing or prevention of mother-to-child transmission (PMTCT) program cannot exist without trained providers, HIV test kits, a variety of essential drugs, and lab facilities. If clients test negative for HIV (meaning they are not infected), there is a need for continued support to ensure they remain HIV negative. This support involves access to sound and balanced information, support in decision making about abstinence, faithfulness and condom use, and access to an affordable supply of condoms.

An effective, comprehensive HIV/AIDS program must be able to guarantee simultaneous availability of services and products for HIV/AIDS prevention, diagnosis, counseling, and treatment. Developing a supply chain that can manage the thousands of different health commodities required to provide a comprehensive range of HIV/AIDS-related services can be challenging, particularly because patients have a vastly increased chance of developing drug-resistant HIV if their ART regimens are interrupted by stockouts, or for other reasons. In addition, if insufficient or poor quality lab reagents are available to perform CD4 or other tests to tell clinicians if the patient’s immune status is at the point where ART is indicated, then the delay in initiation might mean that the patient dies before getting ART. It can also mean that the patient’s status has declined, thus decreasing the impact of treatment once it is started.

**BACKGROUND**
C. NATIONAL GUIDELINES AND POLICY DEVELOPMENT
HIV/AIDS programs operating in a resource-constrained environment are best designed by using a public health approach for prevention, care, and treatment activities, tailored to reflect the local resource environment. Countries trying to treat large populations of people with HIV on limited budgets should use a public health approach to identify the most effective and affordable approaches to diagnosis, testing, care and treatment of people with HIV/AIDS. Implementation of these approaches requires the dissemination of standardized policies and guidelines, which must be developed based on careful assessment and the input of key stakeholders in decision making.

D. NATIONAL ART PROGRAM NEEDS
When assessing the National Antiretroviral Therapy (ART) Program in any country, it is important to discuss all program components. This is independent of the fact that there are many countries in which these programs are organized as vertical programs. For example, PMTCT, voluntary counseling and testing (VCT), home-based care (HBC), and tuberculosis (TB) sites operate separately from ART delivery sites. The design of the supply chain for any of the items used to deliver those services will depend on the source of the commodity and on how, when, and where the commodity is used. Within the Ministry of Health, or national systems, each service delivery component frequently depends on the same supply chain. Thus, an assessment of one component of the system is a reflection of the other.

Programmatically, the components of the program must work together. HIV counseling and testing sites and ART sites are a clear example. It is possible for a country to train health care providers about managing AIDS patients and using ART and to have a sufficient stock of antiretroviral drugs (ARVs) at a given point in time. However, if the residents of the community in which the prepared facility resides are not participating in a counseling and testing program, they will not know that they are HIV infected and will not seek treatment in a timely manner. Therefore, to effectively scale up ART services in a country, all services that are complementary to ART—including HIV counseling and testing, plus treating opportunistic infections (OIs)—must also be expanded or widely available.

E. RELATIONSHIP BETWEEN EPIDEMIOLOGY AND PROGRAM NEEDS
Several factors affect the demand for services in a country and, thus, the requirements for HIV/AIDS commodities. Those factors include the HIV prevalence; the identification of infected groups; and the reach of the current HIV testing, care, and treatment services.

For example, in the majority of sub-Saharan Africa, the epidemic is considered to be a mature one that affects the general population. Transmission is primarily heterosexual, and prevalence tends to be higher than in other parts of the world. In contrast, across Central Asia and Eastern Europe, for example, the epidemic is concentrated or limited to special risk groups (MSMs, sex workers, and IDUs). There is a low overall prevalence of HIV/AIDS among the general population in those areas.

Obtaining accurate data regarding numbers of infections and numbers of people with HIV who need treatment is a challenge in this type of epidemic because many of the risk groups engage in illegal behaviors, which results in a reluctance to get a test for HIV or to disclose either risk or HIV status.

Examples of factors that influence the nature of the HIV/AIDS epidemic in a country—and thus the program and services that are available—including the following:

• HIV Prevalence, which refers to the number of people who are infected with HIV. Because it indicates how widespread the epidemic is in a given population, it affects all other program demands.
• Cases of AIDS, which refers to the number of people who have HIV in a specific country and who have progressed to the stage of HIV called “AIDS” in which they experience a set of signs and symptoms, infections, and conditions.

• Number and Type of HIV Counseling and Testing (HCT) Services Available, which refers to how many different models of HCT exist (for example, VCT, PMTCT, and so on). It determines where and how many HIV test kits and related supplies will be needed.

• Number of ART Sites, which determines the number of antiretroviral drugs (ARVs), drugs for symptomatic relief, and drugs to prevent and treat opportunistic infections (OIs) that will be needed.

• Numbers of Pregnant Women Each Year, Attendance Rates at Antenatal Clinics, and Numbers of PMTCT Programs, which determines the number of pregnant women who might need the services of a PMTCT Program, including test kits, ARVs for mothers and babies, and other medical supplies. These data can be obtained from Demographic and Health Surveys (DHS) and from country data on fertility, average number of children, and attendance at antenatal care (ANC) clinics. In some countries, women are unlikely to come for services, while in others attendance is high.

• Number of Home-Based Care Programs, which influences the demand for all related supplies and drugs for symptom relief.

The usefulness of prevalence data in estimating the number of people likely to progress to AIDS and, therefore, needing treatment varies with the type of epidemic in a country. In countries such as those in sub-Saharan Africa, where the virus is spread largely through heterosexual transmission among the general population, estimating the numbers of people infected with HIV is relatively simple. The prevalence of HIV among pregnant women attending ANCs is—after some adjustments for age, sex, and urban and rural distribution of the population—applied to all adults in the country to get a national estimate of people living with HIV.

However, in countries where the bulk of HIV infections are concentrated within populations whose behavior puts them at especially high risk of contracting and passing on the virus, estimates that are based on prevalence among women at antenatal clinics are likely to be inaccurate. Men who have sex with men and male drug injectors do not get pregnant. Therefore, if they make up a large proportion of those infected with HIV, antenatal-based estimates will miss a significant part of the epidemic.

Individuals wishing to make accurate estimates of HIV infection in concentrated epidemics, moreover, must take a different approach. First, they must decide which population groups are likely to be most at risk of contracting HIV in their national situation because of their sexual or drug-taking behavior. Second, they must estimate how many people in the country engage in each of those high-risk behaviors. They must next consider whether anyone else is exposed to HIV infection by those who engage in such behaviors, even though the exposed people do not themselves engage in any high-risk behavior. They may also wish to consider whether a significant number of people who once engaged in high-risk behavior (and may have been infected with HIV at that time) have since moved out of those groups—for example, either by leaving sex work or by giving up drug injection. Certainly, they must have an idea of the prevalence of HIV infection within each of the population groups at high risk (UNAIDS/WHO, Case Study 2004).

It is generally thought that in higher prevalence countries with generalized epidemics, about 10 percent to 20 percent of HIV-positive individuals in the population are ART eligible, and all are likely to need drugs for OI prophylaxis and treatment. Other factors that are unique to a country or community that affect uptake of HIV/AIDS care and treatment services include the level of stigma, the number of treatment sites, and the risk behaviors that result in HIV infection.
Stigma influences the number of people willing to seek HIV testing and treatment. The fact that there will be significant delays in seeking care when there are situations of high stigma and low accessibility means that those with AIDS who need treatment at a given point in time might be a higher percentage of the total population than the percentage in a situation in which people seek treatment more promptly.

If there are few treatment sites or if people do not know or like the sites that exist, they might also delay seeking care. If the people who are infected are involved in illegal activities such as sex work or injecting drug use, there will probably be delays in seeking both testing and care as a result of the potential personal risk involved. If treatment is delayed, for any of those or other reasons, a higher proportion of HIV-positive individuals who do finally seek care is likely to need treatment at the time of entry into care.

Some country experience and treatment reports, plus anecdotal evidence, suggest that about 10 percent to 20 percent of HIV-infected people who are seeking care in a context such as sub-Saharan Africa will need ART, whereas this figure might be as high as 30 percent to 50 percent in another context, such as in Central Asia or Eastern Europe. In those regions, sentinel surveillance is not useful as an estimate of the number of HIV-infected people. Rather, documentation of those who have tested HIV positive at testing sites can be a guideline as to ART needs.

Because of gross underreporting of HIV infections and cases of AIDS in many countries (for example, people with AIDS documented as being cases of pneumonia or TB), local data might not be valid enough to provide a sound basis for quantification. However, the data do provide a sense of the trend of the epidemic in that country. When one reviews the data for quantification, for example, it is useful to keep in mind that stigma can play a significant role in reducing uptake of services. In addition, stigma around treatment may be more of a barrier in countries with concentrated epidemics. Thus, when one estimates numbers of AIDS cases, it is important to factor in potential uptake rates of both testing and treatment on the basis of issues such stigma and access to treatment.

Another way to determine numbers requiring ART is by looking at service statistics data on attendance rates for the three most frequent opportunistic infections. Once patients are on ART, the number of opportunistic infections decreases as the immune system rebounds. However, in programs where ART has not yet been introduced or where it is available on a very limited basis, service statistics related to treatment of OIs can supplement prevalence data, because those data can be used as a proxy for people requiring treatment. Moreover, service statistics for OI treatment might also be difficult to obtain because many programs are still relatively new, and the data are usually incomplete.

Another issue to consider in quantification is when to estimate the need for changes to first line regimens. In sub-Saharan Africa, current estimates are that patients who do not experience adverse reactions or toxicity to first line regimens will take between three and five years before they need to switch to the second line regimen. However, reactions or side effects resulting from some drugs in the first line regimens will require a switch of one of the first line regimen drugs; current estimates are that about 15 percent of patients on most first line regimens will need to switch at least one drug.

When one looks at national program needs for post-exposure prophylaxis (PEP), factors—such as the current number of reported occupational exposures and data showing whether those reporting occupational or other exposures accept offers of PEP—can form the initial basis for estimates of need. In some countries, PEP is being offered to victims of rape, and estimates would be needed regarding the level of predicted usage in those cases.

A sample tool for estimating program numbers is illustrated in table 1, using local HIV/AIDS data for different subpopulations and different HIV/AIDS service components. (FHI, Assessment and Recommendations, 2004–2005).
TABLE 1. ILLUSTRATIVE HIV COUNSELING AND TESTING PROJECTIONS TO ENROLL 450 PEOPLE LIVING WITH HIV/AIDS (PLWHA) IN THE ART PROGRAM

This equation allows you to calculate the number of HIV tests needed to identify and treat a target number of HIV positive people. This equation allows you to forecast the need for HIV tests for the general population and various high risk groups. Known variables required: 1) Target number to receive ART (as dictated by proposal/goal), 2) Estimated population of HIV positive people (or population x prevalence rate), 3) HIV prevalence in general population and among high risk populations and 4) the CD4 treatment guidelines of the country.

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
<th>I</th>
<th>J</th>
<th>K</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target number to receive ART (CD4 &lt; 200)</td>
<td>Total estimated no. of HIV positive persons that need to be identified via testing to reach 450 people on ART</td>
<td>Prevalence in General Population*</td>
<td>Test Refusal Rate</td>
<td>Total no. of people who need to be tested</td>
<td>% (annual) Refusing Treatment</td>
<td>Adjusted Number of HIV tests needed</td>
<td>Number of HIV tests needed for IDU (prevalence 38.4%)</td>
<td>Number of HIV tests needed for CSWs (4.2%)</td>
<td>Number of HIV tests needed for Seasonal migrant laborers</td>
<td>Number of HIV tests needed for MSM (x3)</td>
</tr>
<tr>
<td>450</td>
<td>2,700</td>
<td>0.5</td>
<td>0.1</td>
<td>5,940</td>
<td>0.10</td>
<td>6,534</td>
<td>3,267</td>
<td>653</td>
<td>3,267</td>
<td>2,178</td>
</tr>
</tbody>
</table>

Explanation

* This is an example only, and does not reflect actual HIV prevalence or situation in Nepal.

Column A: The target number of people to receive ART in a designated geographic area or region.

Column B: Formula: sum(ABS(A5)) Not all people who are HIV positive are ready to start ART. This formula is used to calculate the total number of PLHA who would need to be tested to reach 450 people with CD4 count 200 or lower. The example uses initiation criteria of CD4 < 200. This is determined by multiplying the target number to receive ART by 6. Use the number 6 as a multiplier when using CD4 guidelines < 200. (When using CD4 < 250 multiply by 5, and when using CD4 < 350 multiply by 4.)

Column C: The HIV prevalence level found in the target population.

Column D: The test refusal rate for HIV testing is estimated at 10%. The test refusal rate is likely to be higher for high risk groups. To the extent possible this number should be based on experience with the target population. If unknown, it is better to overestimate to ensure an adequate supply of tests.

Column E: Formula: sum((B5/C5))*1.1 To determine the number of HIV tests needed for the general population, divide the number of HIV tests needed to generate the required number of persons with CD4 < 200 by the HIV prevalence in the general population, and then multiply that number by 1.10 to compensate for the 10% refusal rate.

Column F: Based on evidence, the percent who refuse treatment for one reason or another is estimated at 10%.

Column G: The adjusted number of HIV tests needed is determined by multiplying the number of HIV tests by 1.1 to compensate for the 10% treatment refusal rate.

Column H: Formula: sum((B5/C5)*1.1)*1.1 To determine the number of HIV tests needed for STI clients, divide the number of people who need HIV tests according to CD4 guidelines by the HIV prevalence in the general population X 2, and then multiply that number by 1.10 to compensate for the 10% testing refusal rate. Finally, multiply the total by 1.10 to compensate for the 10% treatment refusal rate.

Column I: Formula: sum((B5/C5)*1.1)*1.1 To determine the number of HIV tests needed for commercial sex workers, divide the number of people who need HIV tests according to CD4 guidelines by the HIV prevalence in the general population X 10, and then multiply that number by 1.10 to compensate for the 10% testing refusal rate. Finally, multiply the total by 1.10 to compensate for the 10% treatment refusal rate.

Column J: Formula: sum((B5/C5)*1.1)*1.1 To determine the number of HIV tests needed for the uniformed services, divide the number of people who need HIV tests according to CD4 guidelines by the HIV prevalence in the general population X 2, and then multiply that number by 1.10 to compensate for the 10% testing refusal rate. Finally, multiply the total by 1.10 to compensate for the 10% treatment refusal rate.

Column K: Formula: sum((B5/C5)*1.1)*1.1 To determine the number of HIV tests needed for MSM, divide the number of people who need HIV tests according to CD4 guidelines by the HIV prevalence in the general population X 3, and then multiply that number by 1.10 to compensate for the 10% testing refusal rate. Finally, multiply the total by 1.10 to compensate for the 10% treatment refusal rate.

This section addresses the main aspects of a comprehensive HIV/AIDS program in somewhat more detail than was included in the introductory section on HIV/AIDS programs.

A. LOGISTICAL IMPLICATIONS OF HIV/AIDS PROGRAMMING TRENDS
In an HIV/AIDS epidemic, a challenge facing donors, policymakers, and program managers is to retain a balanced focus on all components of programs. With limited resources and the pressure of advocacy concerns at any given time, there is often a shift from one area of need to another. Recently, there have been aggressive efforts to redress the fact that treatment for PLWHA in resource-constrained countries was virtually ignored for the first 20 years or more of the epidemic. With the advent of global programs such as WHO’s 3 × 5 initiative; the President’s Emergency Plan for AIDS Relief (PEPFAR); and the Global Fund for HIV/AIDS, TB, and Malaria, antiretroviral treatment has taken center stage. While this is a significant accomplishment for the global community of people infected and affected by HIV, the heavy focus on ART poses a programmatic challenge as the other components within the program fight for attention and resources. It is important for supply chain managers to be aware of current and future trends in programming, because shifts in priority for services will require corresponding changes in demand for commodities.

B. HIV PREVENTION
As treatment programs expand, there has been a risk of diverting attention from the continuing need for prevention programs. The success of treatment programs depends on the success of prevention efforts. Otherwise, programs will be overwhelmed with ever-escalating demands for care and treatment.

Meeting the prevention needs of communities facing HIV/AIDS is a complex challenge. There are three primary modes of HIV transmission:

- Sexual: male-to-female, female-to-male, male-to-male, and female-to-female
- Parenteral: blood transfusion, intravenous drug use (IDU), needle sharing, needle stick accidents
- Perinatal: in utero, during labor and delivery, and postpartum during breastfeeding

Worldwide, sexual transmission is the predominant mode. However, in Asia and Eastern Europe and in subpopulations on other continents, IDU exceeds sexual transmission as the primary mode of transmission.

Prevention programs require the use of behavior change communications, access to condoms, and clean needles and syringes, contextual interventions, and programs to prevent mother-to-child transmission, which includes counseling and testing, plus antiretroviral drugs.
Susceptibility to HIV infection is related to a wide range of social factors such as poverty, culture, gender relations, and lack of education. HIV prevention programming requires strategies and interventions that support behavior change, access to services, a supportive environment, and positive social norms. Core public health services should be organized so that HIV prevention services are delivered at all levels of the system.

Effective prevention can substantially reduce the number of new infections and, therefore, ultimately will lead to a reduction in the number of people who will need treatment. To be effective, prevention programs use behavior change communication strategies that consist of many types of activities, which might include mass media, peer education, local drama, and so on. Programs need to deliver clear and locally tested messages using different channels. They need to tailor messages to the target audience and to deliver them at a high level of intensity over time. The messages must be accurate, consistent across media, and meaningful to the audiences they seek to reach. U.S. donors, in particular, are emphasizing promotion of abstinence, faithfulness, and condoms. Condom programs are the most dependent on commodities and, therefore, are of greatest relevance to supply chain management programs. Ensuring that condoms are accessible, acceptable, and affordable to those who need them is a challenge that must be met if prevention efforts are to be successful.

C. HIV COUNSELING AND TESTING

As an adjunct to prevention interventions, HIV counseling and testing is considered a powerful prevention tool. It is hypothesized that if a person knows his or her HIV status, then a greater likelihood exists that there will be an effort to decrease the risk of transmission to another person. In addition, as people attend services that include counseling, the overall level of knowledge about HIV in a community will increase.

HIV counseling and testing form a critical entry point for many other HIV/AIDS services, including care and treatment, as shown in table 2.

**TABLE 2. HIV TESTING AND COUNSELING**

<table>
<thead>
<tr>
<th>Promote planning for future orphan care and will preparation</th>
<th>Ease acceptance of serostatus and coping</th>
<th>Provide access to ARV treatment</th>
<th>Promote and facilitate behavior change</th>
<th>Provide access to interventions for preventing mother-to-child transmission</th>
</tr>
</thead>
</table>

**HIV Testing and Counseling**

- Normalize HIV/AIDS and reduce stigma
- Facilitate referral to school and peer support
- Increase access to family planning services, including condom provision
- Promote access to early medical care for opportunistic infections and STIs, and to ARVs and preventive therapy for tuberculosis


Although service delivery approaches may differ within and between countries, the recommended public health approach for scaling up HIV counseling and testing (HCT) remains the same: the test is voluntary (the client has the right to refuse), the client must give informed consent, the results are kept confidential, the test is accompanied by counseling, and the quality of the HCT is ensured. (FHI, *Service Delivery Models for HIV Counseling and Testing* 2005).
Several models of counseling and testing are used in different settings, including freestanding clinics, integrated sites, mobile test units, home-based care programs, and so on. Examples of models include the following (Source: CDC/GAP, About Our Work, 2005):

- **Voluntary HIV Counseling and Testing (VCT)** gives clients an opportunity to confidentially explore their HIV risks and to learn their HIV test result. VCT services can be provided in freestanding sites or imbedded within other facilities, such as health centers, workplace settings, and military facilities. The target audience is individuals who are interested in knowing their HIV status and learning how to reduce their risk. The focus of the counseling sessions is on risk assessment; risk reduction; partner referral; and linkages to care, treatment, and support.

- **Couple HIV Counseling and Testing (CHCT)** allows sexual partners to learn their HIV status together as a unit. It is offered at VCT sites but may also be offered in other settings as well, such as prenatal clinics. CHCT is an important intervention because as many as 30 percent of couples in high HIV prevalence countries are serodiscordant, or have one partner who is infected with HIV and one who is not. Counseling sessions focus on discussing risk issues and concerns; risk reduction; and linkages to care, treatment, and support.

- **Provider-initiated HIV counseling and testing** takes place in clinical settings—such as in medical wards and in TB and sexually transmitted infection (STI) clinics—for the purposes of HIV diagnosis and clinical care management. Pre- and post-test counseling sessions focus on recommending and offering the HIV test, obtaining informed consent, using the test results to make medical care decisions or recommendations, and providing appropriate referrals. Provider-initiated HCT is a relatively new phenomenon and has replaced the practice of providers testing for clinical diagnosis without any counseling of the client, or sometimes even without the client’s consent.

- **Testing and Counseling for Prevention of Mother-to-Child Transmission of HIV** occurs in prenatal and labor and delivery settings for the purposes of learning a pregnant woman’s HIV status and, if necessary, providing a PMTCT intervention. Pre- and post-test counseling sessions focus on recommending and offering the HIV test; obtaining informed consent; using the test results to make decisions about PMTCT; and providing appropriate referrals for follow-up care, treatment, and support.

WHO further recommends that four types of testing be clearly distinguished. In countries following such guidelines, there are implications for logisticians, including the calculation of tests needed by TB and STI clinics, a new area of emphasis in counseling and testing programs.

1. **Voluntary Counseling and Testing.** Client-initiated HIV testing to learn HIV status provided through VCT remains critical to the effectiveness of HIV prevention. UNAIDS and WHO advocate for the effective promotion of knowledge of HIV status among any population that may have been exposed to HIV through any mode of transmission. Pre-testing counseling may be provided either on an individual basis or in group settings with individual follow-up. UNAIDS/WHO encourage the use of rapid tests so that results are provided in a timely fashion and can be followed up immediately with a first posttest counseling session for both HIV-negative and HIV-positive individuals.

2. **Diagnostic HIV Testing.** Such testing is indicated whenever a person shows signs or symptoms that are consistent with HIV-related disease or AIDS. The test aids clinical diagnosis and management, including HIV testing for all TB patients as part of their routine management.
3. A Routine Offer of HIV Testing by Health Care Providers (a.k.a provider-initiated). This offer should be made to all patients who are the following:

- Are assessed in a sexually transmitted infection clinic or elsewhere for a sexually transmitted infection (The test will facilitate tailored counseling using the knowledge of HIV status.)
- Are seen in the context of pregnancy (The test will facilitate an offer of antiretrovirals for prevention of HIV transmission.)
- Have potential for mother-to-child transmission
- Are seen in clinical- and community-based health service settings where HIV is prevalent and antiretroviral treatment is available (injecting drug use treatment services, hospital emergencies, internal medicine hospital wards, consultations etc.) but who are asymptomatic

4. Mandatory HIV Screening. The combined UNAIDS/WHO supports mandatory screening for HIV and other blood-borne viruses of all blood that is destined for transfusion or for the manufacture of blood products. Mandatory screening of donors is required before all procedures involving transfer of bodily fluids or body parts.

Advances in HIV testing technology have made simpler and cheaper means of rapid HIV diagnostic tests more available, thereby enabling HIV counseling and testing services to become more widely available and affordable. This advanced technology, in turn, has helped ensure that user-friendly, appropriate HIV tests and supplies are available at lower-level health facilities, thus enabling the expansion of HIV counseling and testing services in general and of VCT services in particular. An effective supply chain to manage and ensure continuous availability of HIV tests and supplies is and has been a critical element in enabling expansion of HIV counseling and testing services.

Commodities for HIV testing and counseling services may include the following:

- HIV test kits
- Automated analyzers (e.g., enzyme-linked immunosorbent assay [ELISA] readers)
- Reagents and controls
- Centrifuges
- Refrigerators
- Test tubes, racks, timers, pipettes, and other laboratory consumables
- Commodities for specimen collection (e.g., vacutainers, lancets, needles, syringes, and plasters)
- Commodities for universal precautions (e.g., disposable gloves, bleach, cleaning supplies, sharps disposal containers for needles and lancets, and waste disposal bags for blood-contaminated materials)
- Safe drinking-water and cups
- Information materials for training and education
- Male and female condoms
Relevant to quantification are the following insights from the WHO Toolkit:

- HIV testing and counseling services are best supported through approaches that are based on integrated HIV/AIDS care, treatment, support, and prevention.

- The rate of HIV testing and counseling uptake may become inextricably linked with access to ARV treatment, as individuals may be encouraged to find out their HIV status if they have access to better treatment options.

- Rapid scaling up of care also requires a diversification and expansion of HIV testing and counseling services linked to clinical care and antenatal care (ANC) settings.

Implementation of HIV testing and counseling entails various approaches, including the following:

- Use of HIV rapid tests in low-volume settings, or those situated away from provincial treatment centers, and in areas of high prevalence and vulnerability to HIV.

- Diversification of sites where testing and counseling can be provided. This diversification implies, for instance, the availability of rapid testing in areas with greatest representation of vulnerable populations (e.g., STI or reproductive health care services, TB services, and IDU services) and in nonclinical areas where prevention may be optimized (e.g., antenatal care and services for young people).

- Outreach and mobile initiatives may be necessary to improve access to HIV testing and counseling among hard-to-reach groups (e.g., IDUs, sex workers, and young people). Although there may be different approaches to service delivery both within and between countries, the principles of the recommended public health approach for scaling up HIV testing and counseling should be common to the varying approaches.

An issue that has received less attention than it merits is the diagnosis of HIV infection in infants under 18 months of age. Although the HIV tests that are used for adults are acceptable in infants above a certain age, which is being further defined at present, the usual antibody tests are not valid in infants. Infants born to HIV positive mothers have about a 35 percent chance of acquiring HIV through pregnancy, labor, delivery, or breastfeeding. When they are born, they have the HIV antibodies passed from the HIV-infected mother, but they may not, in fact, be infected themselves. Until 18 months or perhaps as early as 9 months, it is not possible to test for the virus itself using currently available HIV tests, except by use of polymerase chain reaction (PCR) tests. Those tests require very sophisticated laboratory capability in terms of equipment, special room setups, and trained personnel.

Many resource-constrained countries have only one laboratory in the country that is capable of doing PCR. One new technique that is increasingly used involves dried blood spots that are transported to such a lab. The required commodities vary from those for the usual HIV antibody tests. It is important for logisticians to be in communication with policy makers who develop HIV testing strategies, because all plans to use this technology—be it dried blood spot PCR or the usual PCR (direct testing of the blood specimen from the baby)—should be included in supply chain management and planning to ensure the availability of a sufficient quantity of PCR reagents. As a recent example, some countries’ governments declared a policy of universal access to PCR testing for all infants, which resulted in an unexpected high demand for infant testing and PCR reagent stockouts.

Widespread access to treatment could bring millions of people into health care settings, thus providing new opportunities for health care workers to deliver and reinforce HIV prevention messages and interventions. Improved access to HIV testing provides an entry point to both prevention and treatment services; it also
provides a unique opportunity to identify and target the infected, vulnerable, and uninfected with more appropriate interventions.

Just as prevention programs are unlikely to achieve full impact in the absence of treatment, so too is the impact of treatment programs reduced if vigorous prevention efforts are absent. Without effective prevention, the number of people requiring care and treatment will grow each year. As more and more people are kept alive with ART, the treatment burden will become enormous unless effective prevention reduces the number of people becoming newly infected. Prevention makes treatment affordable, and treatment can make prevention more effective.

D. PREVENTION OF MOTHER-TO-CHILD TRANSMISSION

Nearly 2,000 babies are born with HIV each day because their HIV-infected mothers do not get the treatment needed to stop transmission (WHO 2006). PMTCT is the term used to describe programs and interventions that are designed to reduce the risk of mother-to-child transmission (MTCT). Such programs are especially valuable because most HIV-infected children acquire the infection through MTCT, which can occur during pregnancy, labor and delivery, or breastfeeding.

PMTCT programs are built around four pillars:

• Primary prevention of HIV infection among women and their partners
• Prevention of unintended pregnancies among HIV-infected women
• Prevention of HIV transmission from HIV-infected women to their children
• Provision of treatment, care, and support for women living with HIV/AIDS, their children, and their families

To accomplish these pillar goals, a PMTCT program encompasses the following components:

• Family planning
• HIV testing and counselling
• Antiretroviral treatment for prevention of MTCT
• Safer delivery practices
• Safer infant-feeding practices

In addition, the program must develop strong linkages so that the mother who is positive and her child are followed after delivery for care and treatment. At present, many programs are not designed to ensure that mothers and their infants are monitored for HIV symptoms and treatment needs after delivery of the baby. Antenatal care (ANC) centers can and should serve as entry points to care and treatment services, including ART for women who need it. In most ANC settings, an HIV test is routinely offered, and some country programs require pre-test counseling of the mother. In other settings, an “opt-out” approach is adopted where women are asked specifically whether they do or do not want to be tested for HIV. Evidence has shown that routine testing or an opt-out approach is more successful in ensuring HIV counseling and testing for pregnant mothers than is an “opt-in” approach.

Short-term ART is an effective and feasible method of preventing MTCT of HIV. Initially, a complicated regimen was used, until studies showed that a single dose of nevirapine given during labor, followed by a dose for
the child, was just as effective as the regimen. Recently, however, the concern has been focused on the possible emergence of nevirapine resistance for mothers exposed to single-dose nevirapine and then enrolled on a nevirapine-containing ART regimen later. Recent data also show that a combination of zidovudine (AZT) and nevirapine (NVP) can be more effective with less risk of resistance. Therefore, some countries, where it is feasible, are beginning to use this combination.

To ensure provision of a minimum package of care in ANC centers, programs need to provide many more products than just these two antiretroviral drugs. See appendix 2 for a detailed list.

Additionally, to be the most effective, PMTCT interventions should make a concerted effort to publicly acknowledge that both mothers and fathers have an impact on transmission of HIV to the infant. Emphasis should be placed on making sure both partners are aware of the importance of safer sex throughout pregnancy and breastfeeding. Both partners should be tested and counseled for HIV, and both partners should be made aware of—and provided with—PMTCT interventions to the greatest extent possible.

E. POST-EXPOSURE PROPHYLAXIS

The accidental or unintended exposure to HIV infection can be treated with post-exposure prophylaxis (PEP), if recommended by a physician. PEP for HIV is the use of antiretroviral drugs as soon as possible after a high-risk exposure to HIV to reduce (but not to eliminate) the possibility of HIV infection. PEP is a four-week program of two or three ART medications taken several times a day.

Treatment should be started promptly, preferably within the first several hours after an exposure. It should be administered within 48 hours of a high-risk exposure (not to exceed 72 hours). After 72 hours, PEP is considerably less effective in preventing HIV infection. Therefore, the sooner PEP is administered, the more effective it is.

According to the Centers for Disease Control and Prevention (CDC), effectively delivering PEP after high-risk exposures requires prompt evaluation of patients and consideration of biomedical and behavioral interventions to address current and ongoing health risks. This evaluation should include determination of the HIV status of the potentially exposed person, the timing and characteristics of the most recent exposure, the frequency of exposures to HIV, the HIV status of the source, and the likelihood of concomitant infection with other pathogens or negative health consequences of the exposure event.

A 28-day course of highly active antiretroviral therapy is recommended for people who have had non-occupational exposure to blood, genital secretions, or other potentially infected body fluids of a person known to be HIV infected when that exposure represents a substantial risk for HIV transmission and when the person seeks care within 72 hours of exposure (e.g., in the case of rape). When indicated, antiretroviral PEP should be initiated promptly for the best chance of success. No evidence indicates that any specific antiretroviral medication or combination of medications is optimal for use as PEP, and protocols differ from one country to the other.

Some countries are using two drugs regimens for “low-risk” exposures and three drugs regimen for “high-risk” exposures. Some are using AZT+3TC with or without NVP. Others use d4t+3TC with or without NVP. Some countries are using a protease inhibitor, such as indinavir, as the third drug for high-risk exposures.

In the United States, certain preferences exist for drugs and combinations, including efavirenz and lamivudine, or emtricitabine with zidovudine or tenofovir (as a nonnucleoside-based regimen). Another preferred regimen includes lopinavir/ritonavir (coformulated in one tablet as Kaletra®) and zidovudine with either lamivudine or emtricitabine. Different alternative regimens are possible as well (CDC, Antiretroviral Postexposure Prophylaxis 2005).
For occupational exposure, health workers usually start taking medications within a few hours of exposure. Usually the exposure is from a “needle stick.” Such exposures occur when a health care worker accidentally gets jabbed with a needle containing potentially HIV-infected blood.

In the past few years, community activists and researchers began asking why PEP should not be automatically administered after HIV exposures in cases such as rape or when a condom breaks during sexual intercourse. In most developing country programs, exposures such as those that are not directly related to an occupational setting are not addressed in the national treatment guidelines and are still in a stage of debate.

**F. CARE AND TREATMENT**

The purpose of HIV/AIDS care and treatment programs is to ensure equitable access to diagnosis, medical care, pharmaceuticals, and supportive services; to reduce morbidity and mortality from HIV/AIDS and related complications; to promote prevention opportunities within care, treatment, and support clinical encounters; and to improve the quality of life for adults and children living with HIV/AIDS and their families.

Providing HIV/AIDS care to people living with HIV and AIDS and to their families requires a broad range of services that includes not only medical care and treatment, but also supportive services to ensure adequate nutrition; psychological, social, and daily living support; and prevention messages wherever the opportunity arises. The following components form a comprehensive package of care and treatment services:

- Medical and nursing care (counseling and testing; prophylaxis of OIs; treatment of OIs and HIV-related illnesses; TB control; STI management; management of HIV disease and ART; palliative care; access to HIV-related drugs; PMTCT services; clinical HIV/AIDS care for mothers and infants; support systems, such as labs and drug management systems; nutritional support; health education; adequate universal precautions; and PEP)

- Psychological support (services to meet emotional and spiritual needs)

- Socioeconomic support (material and social support to ensure that nutritional and daily living needs are met)

- Support for orphans and vulnerable children

- Involvement of PLWHA and their families in service design and evaluation

- Respect for human rights and legal needs

Care and treatment are part of a continuum of care and should be linked to other HIV/AIDS interventions. In addition to the commodities, there is a need for laboratory support, supply chain management, and services and training of the staff and patients.

The care that is needed by the members of a community begins with prevention of HIV infection and includes different services for community members depending on their needs at different points in time. Programs best serve the community if they include components along a continuum of care (as depicted in figure 1).

If a client tests HIV positive, the client will need counseling and psychosocial support about issues such as how to tell a spouse, a child, or other family members about the diagnosis; where to get treatment; and how to deal with the feelings associated with a diagnosis of HIV. This client demands support from the system, his or her family, and the community, as well as referral to social and medical services. At the time he or she requires prevention or treatment of OIs, the health system will again require trained staff, supplies, and drugs.
A unique feature of HIV disease that distinguishes it from the problems that public health has been addressing in resource-constrained countries for years is that it is a chronic disease. Public health programs are much more accustomed to addressing acute illnesses. HIV care requires a chronic disease management approach. In brief, the principles of chronic case management include the following:

- The patient and health provider must work together as a team.
- Care requires regularly scheduled visits to monitor disease status and treatment effects.
- Care providers need care and support to prevent burnout.
- Treatment is life-long so motivation and adherence are critical.

**G. TREATMENT OF OPPORTUNISTIC INFECTIONS**

The prevention and treatment of OIs plays an essential part in the management of AIDS. There are a few OIs that occur most frequently in PLWHA. In some “high-prevalence” countries, it is recorded that about 80–90 percent of all TB cases are co-infected with HIV. (WHO, TB/HIV Co-Infections, 2005) This high coinfection rate means that the majority of HIV/AIDS patients will likely have some form of TB—pulmonary or extra pulmonary. Regardless of type, the treatment protocol is the same.

The second most frequent OI is oral or oesophageal candidiasis. From a supply chain perspective, again, it is important to understand that treatment is frequently the same regardless of location (oral, esophageal, etc.) of the fungal infection.

The third most frequent infection is PCP (pneumocystis carinii pneumonia). Around 40 percent of patients develop PCP if not on ART (WHO, Clinical Aspects of HIV/AIDS, 2005). A more detailed description of common opportunistic infections can be found in appendix 3.

Some opportunistic infections, such as oral candidiasis, pulmonary TB, and herpes, can be treated when a minimum level of health infrastructure is present. Diagnosis can be made by symptoms or by use of a simple microscope. Another point to keep in mind is that after treatment, and in the absence of ART, such infections can and often do recur, so that patients experience several episodes of an infection.

For OIs like malignancies, toxoplasmosis, or cryptococcus infections, data is usually only available at the tertiary-level facilities. Those infections are less frequent; they occur at the advanced stage of AIDS and cannot be diagnosed without sophisticated equipment and highly specialized cadre. Once diagnosed, individuals should be put on lifelong treatment, but usually do not live longer than a year. Treatment for those conditions often requires specialized drugs, which may not be routinely available at district hospitals and lower-level health facilities. Some of those drugs (e.g., gancyclovir) can cost more than ARV drugs and thus can be prohibitively expensive to patients.

For persons with such infections, there is a need to provide for a number of additional “support medications,” such as painkillers, iron substitutes, folic acid, Imodium for diarrhea control, etc. The majority of drugs for treating opportunistic infections are basic essential medicines that should be routinely maintained at district hospitals and primary health care facilities. Those drugs are also used in routine clinical practice and in non-AIDS related cases. They are almost never a part of vertical AIDS programs.

Drugs for TB are usually managed under a National TB Program. Because of the public health risks associated with uncontrolled spread of TB, the program is traditionally a vertical one, with dedicated funds for procurement and separate procedures for managing commodities.
H. PROVISION OF ANTIRETROVIRAL THERAPY

Making ART available and widely used at the global level is one of the largest efforts that the international community has ever taken to reduce human suffering caused by an incurable communicable disease. Although not a cure and when used effectively, ART can decrease illnesses resulting from HIV, decrease AIDS-related mortality, improve quality of life, and decrease risk of transmission. However, providing treatment for those in need on such a large scale has significant challenges, and it is critical that all people involved should be ready to share and learn from their own experiences and from those of others. This approach will help to facilitate the expansion of effective treatment for people who need it sooner rather than later. By instituting large-scale treatment programs while continuing strong prevention efforts in communities, and by reaching both those who are still HIV negative and those who are already infected, the goal to stop the spread of HIV while providing effective life-prolonging treatment for PLWHA.

There are several essential elements of an effective ART program, including the following:

- Country preparedness
- Community preparedness
- Effective care systems, including sufficient numbers of trained providers, rational guidelines, and accessible sites and services
- Adequate site physical capacity
- Referral systems and linkages
- Patient adherence support
- Health management information systems
- Quality laboratory systems
- Reliable access to appropriate ARVs
- Ongoing monitoring, evaluation, and quality management to ensure effective care

1. Program Issues: Access and Uptake. Putting ARVs into pharmacies does not guarantee that PLWHA will be able to access care and treatment. Many factors determine whether people in a community will seek care at a site that offers ART. Those factors include the fee policies of the clinic, access to testing, stigma in the community toward those infected with HIV, transportation, and many other issues. In addition, community awareness of the availability of ARVs and knowledge about their effectiveness and about how to access them is also critical.

Affordability is a major barrier to accessing treatment in the contexts where patients are expected to pay for all or some of the costs of treatment. Provision of ARVs and related diagnostic and monitoring tests free of charge increases uptake of ART. The extent to which patients will be expected to pay for the lab tests, the drugs, or both influences not only their first access to ART but also their ability to continue once they are placed on treatment. Cost of treatment for OIs and laboratory tests may remain an obstacle to access to treatment even for people living with HIV/AIDS who receive ART free of charge. A required financial contribution from patients toward the cost of treatment may be even more of a barrier where more than one person is infected in a household.
Ensuring that people with HIV/AIDS can afford medicines, including ART, is critical. Although ART has fallen in price to U.S. $140 per year, this amount is still too expensive for people living on the equivalent of U.S. $1–2 per day. Evidence suggests that in Africa about 10 million people face impoverishment and about 27 million face severe financial hardships caused by the costs of health care. Countries with low GDP, high HIV prevalence, weak health infrastructure, and limited resources cannot expect to build a large-scale ARV program in the short or medium term without external assistance.

Evidence suggests that the availability of treatment can go beyond helping the individual patient. ART programs increase uptake of services such as counseling and testing, PMTCT, and prevention education. Treatment can also change community perceptions of HIV/AIDS and PLWHA. People who were previously a burden on their families can go back to work and can contribute to the community. Hopelessness in communities overwhelmed for years by people dying of AIDS can be turned to hope as they see that people who were wasting are now gaining weight, look years younger, and are interacting actively with their families and in the community. Such changed perceptions can lead to a decrease in the stigma associated with HIV and to an increase in the willingness to talk about HIV and, thus, perhaps to improve prevention efforts as hope increases and as dialogue becomes less threatening.

However, it is also important to realize that the capacity of many ARV programs is still smaller than the population in need of immediate treatment. Particularly in high-prevalence settings, programs are not able to meet demands for treatment to all of those who can benefit. A number of approaches to set priorities for treatment have been tried, including community education and involvement of PLWHA in program design, committees to review patients needing treatment, and a push to expand sites beyond the initial ARV clinics. In addition, because many PLWHA do not yet need ARVs, additional community and consumer education on clinical criteria for ARV (such as CD4 counts) and on the role of healthy lifestyles is also important to ensure that people understand who is eligible and who can wait.

Therefore, assistance at the site and program level will need to focus on capacity building to increase treatment at the site, to expand treatment to other clinics, and to ensure that there are adequate funds for an uninterrupted supply of appropriate ARVs, lab reagents, and OI drugs. For example, one-time donations are not sufficient for most ART programs.

2. ARV Drugs and Patient Management Issues. Antiretroviral drugs inhibit the growth and replication of HIV at various stages of its life cycle. They do not eradicate (“cure”) HIV, and so they currently need to be taken for life. Response to treatment is measured both through lab tests and through clinical exam and history. Success is defined as increasing the CD4 cell count (a marker of improving the immune system), decreasing the HIV viral load (the amount of HIV found in the blood) ideally to below the level of detection, and improving health (such as gaining weight) and decreased illnesses and morbidity related to HIV. When used in an appropriate combination of at least three ARVs, the medications can be very strong. However, success is limited in the real world by challenges related to the drug’s side effects, the need for near-perfect adherence, and the risk of the virus developing resistance to one or more of the ARVs.

Four main classes of antiretroviral medications are currently used to treat HIV and AIDS, with multiple types of ARVs within three of the four classes (see table 3). Those classes are—

1. Nucleoside and nucleotide reverse transcriptase inhibitors (NRTIs)
2. Non-nucleoside reverse transcriptase inhibitors (NNRTIs)
3. Protease inhibitors (PIs)
4. Fusion inhibitors (FIs, which are not available currently as an oral medication)
### TABLE 3. TYPES OF ARV DRUGS (GENERIC AND U.S. BRAND NAME, AS OF MARCH 2006)

<table>
<thead>
<tr>
<th>NRTIs</th>
<th>NNRTIs</th>
<th>PI</th>
<th>FI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abacavir (ABC, Ziagen®)</td>
<td>Efavirenz (EFV, Sustiva®)</td>
<td>Amprenavir (APV, Agenerase®)</td>
<td>Enfuirtide (T20, Fuzeon®)</td>
</tr>
<tr>
<td>Didanosine (ddI, Videx®)</td>
<td>Delavirdine (DLV, Rescriptor®)</td>
<td>Indinavir (IDV, Crixivan®)</td>
<td></td>
</tr>
<tr>
<td>Lamivudine (3TC, Epivir®)</td>
<td>Nevirapine (NVP, Viramune®)</td>
<td>Lopinavir /Ritonavir (LPV/r, Kaletra®)</td>
<td></td>
</tr>
<tr>
<td>Stavudine (d4T, Zerit®)</td>
<td></td>
<td>Nelfinavir (NFV, Viracept®)</td>
<td></td>
</tr>
<tr>
<td>Zalcitabine (ddC, Hivid®)</td>
<td></td>
<td>Ritonavir (RTV, Norvir®)</td>
<td></td>
</tr>
<tr>
<td>Zidovudine (AZT, Retrovir®)</td>
<td></td>
<td>Saquinavir, soft gel (FTV, Fortovase®)</td>
<td></td>
</tr>
<tr>
<td>Tenofovir (TDF, Viread®)</td>
<td></td>
<td>Fosamprenavir (Lexiva®)</td>
<td></td>
</tr>
<tr>
<td>Emtricitabine (FTC, emtriva®)</td>
<td></td>
<td>Atazanavir (ATV, Reyataz®)</td>
<td></td>
</tr>
</tbody>
</table>

NRTIs inhibit the HIV enzyme reverse transcriptase, which is essential for viral replication. Those drugs are structurally similar to nucleosides (building blocks of RNA). When inserted in place of the natural nucleoside, they block replication of the virus. A combination of two NRTIs form the backbone of all current first line combinations included in the WHO guidance and in other treatment guidelines.

NNRTIs (or “non-nukes”) also block reverse transcriptase through a mechanism different from the NRTIs. The non-nukes are also very potent, but viral resistance can develop through a single change in the viral RNA, which knocks out the entire class. This resistance can even occur after a single dose if given without other ARVs (e.g., single-dose nevirapine for PMTCT).

Protease inhibitors obstruct the enzyme required to cut the viral proteins before final virus assembly. They are also very potent; for many of them, resistance takes longer to develop than for NNRTIs. They have a number of characteristics that complicate their use, including side effects, drug interactions, and cost and need for a cold chain for some of them. In resource-limited settings, these drugs are largely reserved for second line treatment of individuals for whom first line treatment is no longer working.

Fusion Inhibitors bind to HIV and prevent the virus from infecting healthy cells in the body. As of now, they are used in drug-resistant cases as a salvage therapy.

The use of ARVs requires a system that supports providers and patients to ensure near-perfect (>95 percent) adherence. This requirement is because studies have shown that lower rates of adherence are more likely to result in the virus developing resistance to the ARVs currently being used. In addition, this resistance can weaken or even eliminate the potency of other ARVs from the same class (“cross-resistance”). Multiple barriers exist to adherence, include drug side effects, cost of treatment, access to the clinic, fear of disclosure if family or friends see the ARVs, and many others.

Side effects and toxicities related to ARVs not only threaten adherence, but also can be life threatening, thereby requiring a change in the ARV that is the cause. Side effects can occur early in treatment (e.g., rash caused by nevirapine) or can be delayed (such as lactic acidosis, neuropathy, and changes in body shape).
(a). Current guidelines on what and when to start. WHO has produced guidelines for scaling up ART provision in resource-poor settings. The guidelines address issues such as when to start therapy; what the recommended first line and second line regimens are; and what the regimens are for pregnant women, children, and TB patients. In addition, there are recommendations for promoting adherence, monitoring resistance, and monitoring the clinical and laboratory use of ART. Simplified treatment regimens and laboratory monitoring and the inclusion, since April 2002, of 12 ARVs in the WHO Model List of Essential Drugs (WHO 2002) have significantly reduced the complexity of treatment.

(i). When to start ART. The decision to start antiretroviral treatment is based on weighing the potential benefits of treatment (decreasing risk of death and illness, improving health status) and the risk of disease progression with the toxicities and costs of ART. Therefore, not everyone with HIV needs ART currently, although most will eventually need to start treatment. In resource-limited settings, the decision to start is based on clinical assessment and, where available, on CD4 counts. Those factors determine if therapy should be started or can be or should be delayed. Most of the countries have in their guidelines additional specified “eligibility criteria,” and those criteria must be considered along with individual patient readiness for starting treatment and for making a lifelong commitment to taking ARVs. In the case of infants and young children, “patient” readiness refers to readiness of the responsible person who will be administering the ARV.

WHO recommends that—in resource-limited settings—the adolescents and adults who have had an AIDS-defining condition (as defined by the WHO stage 4) should start treatment regardless of CD4 count. Where CD4 counts are available, any person who has a CD4 cell count <200 cells/mm3 should also be started on treatment. In the absence of access to CD4 cell counts, using a total lymphocyte threshold in combination with the presence of symptoms (WHO stages 2 or 3) will also provide indications to start ART. Some individual countries have modified those criteria, and one should be familiar with such recommendations when working in that area. The newest draft of WHO’s clinical staging guidelines is an important reference. (WHO, Revised WHO Clinical Staging, 2006).

National guidelines exist for standardized first line and second line regimens, eligibility criteria for starting ARV therapy, and patient monitoring. The guidelines are essential to assist planning of drug procurement, to limit the number of drugs to manage, to predict patterns of resistance, to simplify training of health care providers by using standard clinical management protocols, to educate patients, and to develop simple and effective monitoring and evaluation systems. Although experience has shown that it is feasible to follow standardized treatment regimens in resource-poor settings, while ensuring compliance with guidelines, can be a challenge. (See table 4.)

**TABLE 4.WHO GUIDELINES FOR INITIATION OF ART**

<table>
<thead>
<tr>
<th>The following are a summary of current WHO guidelines for initiating ART:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• WHO Stage IV of HIV disease (clinical AIDS), regardless of CD4 count</td>
</tr>
<tr>
<td>• WHO Stages I, II, or III of HIV disease, with a CD4 count below 350/mm</td>
</tr>
<tr>
<td>• WHO Stages I, II, or III of HIV disease, with a CD4 count below 350/mm</td>
</tr>
</tbody>
</table>

(ii). What to start. Guidelines also exist on what combination of ARVs should be started (“first line”). The guidelines are based on a combination of efficacy and toxicity data, cost, availability, and the need to be able to plan for second line treatment for patients for whom first line treatment has failed. In addition, guidelines specify when—and with what—ARV switches should occur for toxicity, drug interactions, or other conditions. For patients who have already been on ARVs, clinicians should obtain the client’s ARV history before choosing a regimen. Other considerations include other medications which the patient is taking, current (or planned) pregnancy, and history of toxicity with prior ARVs.

Recommendations are that ART should always be initiated with at least three drugs, including two NRTIs in combination with a PI or an NNRTI. Studies are still ongoing to evaluate the role of triple NRTIs, although initial results have been disappointing. Fixed-dose-combination drugs have been created to decrease the number of tablets or capsules that a patient has to take. In addition, as new research continues to expand understanding of how best to use and sequence ARVs, those recommendations are likely to change.

The most commonly and currently recommended first line regimens in resource-limited settings as of March 2006 include those shown in table 5.

<table>
<thead>
<tr>
<th>TABLE 5. COMMONLY RECOMMENDED FIRST LINE ART REGIMENS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stavudine+Lamivudine</td>
</tr>
<tr>
<td>OR PLUS OR</td>
</tr>
<tr>
<td>Zidovudine+Lamivudine</td>
</tr>
<tr>
<td>OR PLUS EFV</td>
</tr>
</tbody>
</table>

Drug considerations and logistics implications when choosing an ARV Regimen include the following:

- Cost
- Availability of a formulation
- Frequency of side effects and toxicities
- Frequency of dosing
- Dietary restrictions
- Storage requirements (particularly cold-chain needs)
- Prior ARV exposure
- Frequency of opportunistic infections (particularly TB)
- Prevalence of liver disease (hepatitis B and C)
- Other medications (particularly TB drugs)
- Existence of a fixed dose combination
ART treatment is not the only life-prolonging effort. Prevention and treatment of opportunistic infections is critical, and such actions rely on the availability of drugs such as cotrimoxazole and fluconazole. In addition, maintaining a healthy lifestyle, including access to good nutrition and medical care, is also important but remains a challenge for many individuals with HIV infection.

(iii). When to change ARVs. There are a number of situations in which one or all of the drugs in an ART regimen need to be changed. The most common cases include the following:

- Need to change a single ARV
  - Toxicity: change the most likely causative agent.
  - Drug interaction: change the specific ARV (e.g., for TB treatment containing rifampin, change nevirapine to efavirenz).
  - Pregnancy: change from efavirenz (teratogenic).

- Need to change the entire regimen
  - Treatment failure: change to second line treatment or salvage regimens

(a). Side effects and toxicity. Patients on ART regimens may develop signs of drug intolerance or toxicity. If this toxicity is linked to a single drug in the regimen, then that drug can be discontinued and replaced with a substitute according to the national protocol. This toxic reaction can constitute a medical emergency (such as severe rash with nevirapine or lactic acidosis) and must be done quickly.

If side effects are not life threatening but are intolerable enough to compromise adherence and if a specific agent cannot be identified, then switching the entire regimen may be appropriate. One of the challenges in rapidly scaling up ART in resource-limited settings and in instituting wide-spread usage of triple fixed-dose combinations as the first line regimen is the identification of the specific drug in the regimen that is responsible for side effects.

(b). Switching to Second Line Regimens. Treatment failure is defined as the following:

- Clinical failure: By definition, clinical failure is the progression of disease with the development or recurrence of opportunistic infections or malignancy occurring three months or more after the initiation of the therapy. Clinical events that occur within three months or at initiation may result from a strengthening of the immune response to recognize infections that were present before ART (known as the immune reconstitution syndrome).

- Immunologic failure: This failure is represented by an inadequate CD4 count increase, or a significant drop from peak CD4 counts, or return to pre-ARV-baseline or lower CD4 counts.

- Virologic failure: This is demonstrated by the failure to suppress viral replication to below levels of detection or return of detectable viremia after suppression.

In general, virologic failure occurs initially, followed by a drop in CD4 counts (immunologic failure) and then by disease progression (clinical failure). The ability to detect the different types of failure will depend on lab capacity.
If a patient should switch his or her regimen because of treatment failure, then the switch should be from
the original first line combination to a completely new standardized second line regimen. The choice will
depend on the ARVs included in the first line treatment, the availability and cost of second line ARVs, the
supply chain implications, and other factors.

Table 6 gives the list of possible second line regimens according to current WHO recommendations, but it
will likely be updated soon.

### TABLE 6. ALTERNATIVES FOR SECOND LINE ART REGIMENS

<table>
<thead>
<tr>
<th>Regimen</th>
<th>TDF+ddI+LPV/r</th>
<th>TDF+ddI+LPV/r</th>
<th>ABC+ddI+LPV/r</th>
<th>TDF+ddI+NFV</th>
<th>TDF+ddI+SQV/r</th>
<th>ABC+ddI+NFV</th>
<th>TDF+abc+LPV/r</th>
</tr>
</thead>
</table>

3. **Special Populations.** Provision of ART also must be considered within the context of special populations,
for whom the general guidelines may not be appropriate. These include tuberculosis patients, pediatric
patients and pregnant women.

(a). **Tuberculosis patients.** In areas with high TB prevalence, it is also important to consider the potential
for drug interaction, the overlapping toxicities, and the challenges to adherence, which are based on the
number of pills that patients need to take for both TB and HIV treatment. The anti-TB drug rifampicin induces liver enzymes that the body uses to break down some anti-HIV drugs. This breakdown results in reduced levels of ARV drugs in the body, which may lead to drug resistance. Therefore, most guidelines have specific recommendations regarding the choice of ARVs and the timing of ART initiation in patients who are starting or are already on TB treatment.

(b). **ARVs in the pediatric population.** In many country programs, pediatric ART provision lags significantly behind the provision of ART to adults. The reasons are many. Diagnosis of HIV in infants and children, especially those under 18 months of age, is difficult (as described earlier). Challenges include having access to appropriate testing, ensuring that all exposed infants are tested, and overcoming stigma and fear among parents and other careproviders through education and community outreach. In addition, for children who present with illness, the mother may be reluctant to test her infant or child if she has not addressed her own HIV status.

Other factors—besides diagnosis—that have resulted in limited treatment for children include the cost and lack of availability of pediatric ART formulations, as well as the inadequate numbers of trained providers who can prescribe, manage, and support children with HIV and their families. The lack of fixed-dose combinations (FDCs) is also an obstacle for good treatment adherence, as well as supply chain and storage implications of liquid formulations. A major challenge for supply chain managers includes estimating the changing needs as children grow. Pediatric treatment includes the need to redose
children frequently as they gain weight, as well as the need for multiple formulations as children become able to swallow pills and so are changed away from the more-expensive and more-difficult liquids.

WHO has also developed guidelines on when to start treatment for infants and children. Those guidelines include the clinical criteria for infants and children with confirmed HIV infection:

- WHO stage 3. Treat all children irrespective of CD4. In children >18 months of age, this treatment can be guided by CD4, when available.
- WHO stage 2. Treatment depends on the CD4 count and the percentage of total lymphocyte count CD4/TLC guided.
- WHO stage 1. Treat only if n = meets CD4 count or CD4 percentage criteria.
- Treat all children under 1 year of age.
- The clinician should discuss the risks and benefits of a treatment regimen that involves HIV-infected children and their caregivers, thereby allowing them to make an informed decision regarding initiating therapy. If the potential risks outweigh the benefits, then treatment may need to be deferred.

(c). Pregnancy. A number of ARVs are contraindicated in pregnancy because of teratogenicity or toxicities. Efavirenz should not be used in women who are pregnant or are planning on becoming pregnant because of risks of birth defects. The combined use of DDI and D4T is also not recommended for pregnant women because of higher risks of fatal liver toxicity. Finally, the use of nevirapine as part of multidrug ART to prevent MTCT is not recommended for women who are starting treatment with CD4 cell counts >250 because of increased risk of liver toxicity.

4. When Second Line Treatment Fails. A patient’s best chance of good clinical outcomes is when the first line treatment is successful. A second line regimen is typically less effective because the virus may have developed resistance to this class of drugs. If the second line of drugs fails, then salvage therapy may have to be considered. Salvage regimens are expensive, and their clinical benefit may be limited. In many resource-limited settings, those regimens are not available. Some data suggest that continuing a failing second line regimen may still offer some clinical and survival advantage, but this approach needs to be weighed against toxicity, cost, and overall access to second line treatments. This area is where research is clearly needed within resource-limited settings to determine appropriate management and to develop cheaper and more-accessible salvage therapy options.
I. PALLIATIVE CARE

Definitions of palliative care have varied over time. Emphasis in the past has focused on care to provide comfort to patients needing what people in the United States term hospice care. The U.S.-funded PEPFAR program recently expanded its definition to one that says that palliative care is as follows:

… patient and family-centered care. It optimizes the quality of life of adults and children living with HIV through the active anticipation, prevention, and treatment of pain, symptoms, and suffering from the onset of HIV diagnosis through death. Palliative care includes and goes beyond the medical management of infectious, neurological, or oncological complications of HIV/AIDS to comprehensively address symptoms and suffering throughout the continuum of illness. The means by which this is achieved will vary according to stage of illness but always with the understanding that quality of life involves clinical, psychological, spiritual, and support care. (OGAC, The President’s Emergency Plan for AIDS Relief 2005).

The WHO definition says that “Palliative care is an approach which improves the quality of life of patients and their families facing life-threatening illness, through the prevention, assessment and treatment of pain and other physical, psychosocial and spiritual problems (WHO, Palliative Care, 2006).”

The goals of palliative care are to provide support and care that make life comfortable for patients throughout all phases of the disease so they can live as fully and comfortably as possible. The underlying principles include the following:

- Management of symptoms
- Psychosocial support
- Teamwork and partnership
- Appropriate ethical considerations
- Realistic goals that will sustain hope

The course of HIV/AIDS is highly variable and unpredictable with a wide range of possible complications, rates of progression, and survival. Some patients remain free of serious symptoms for a long time, while others experience periods of increasing dependency with episodes of acute illness or suffer non-life-threatening complications throughout their illness.

The medical management of people with AIDS is a balance between acute treatment and trying to control symptoms. Most people at the end stage of AIDS suffer from many symptoms, including pain. There is often strict legal control on analgesics such as codeine and other opiates. In many countries, the analgesics can be prescribed only by doctors. A balance is needed between, on the one hand, increasing access to adequate pain relief for people with AIDS and, on the other hand, careful supervision and record keeping of prescription of opiate analgesics.

In some countries, home-based care (HBC) programs use a so-called “home care package,” which are sets of consumables such as gloves, aprons, disinfectants, painkillers, Nystatin for oral thrush, and Imodium tablets for diarrhea. Others designate a central place where HBC workers can get goods as they need them, according to their clients’ households’ needs. In this way, there is not as much wastage by pre-packaging kits of goods that might not be used or might expire. Some country programs occasionally receive donations of the needed supplies.

See appendix 4 for a more detailed list of commodities used for provision of palliative care.
3. HIV/AIDS SERVICE DELIVERY:
CRITICAL ELEMENTS
AND CHALLENGES

The pyramid in figure 2 presents another framework for depicting the continuum of care and the need for comprehensive services within HIV/AIDS programs. Specifically, it illustrates the types of commodities needed to support HIV/AIDS prevention, care, and treatment services. The pyramid does not imply that one category is more important than another; rather, it reflects loosely the order in which the various commodities have been made available. It, in turn, follows the order in which HIV/AIDS programs historically have been implemented. The pyramid, starts at the base with condoms and other products for prevention, followed by test kits for HIV testing and drugs for treatment of STIs, PMTCT, and palliative care, and finally ending with the antiretrovirals that are needed for the widespread scale-up of ART. For each category, there are associated human resource requirements and needs for laboratory reagents and consumables. An effective national program needs all of those types of commodities. Each constituent program—whether it be treatment, care, or prevention—will not need them all, but will need, at the very least, to be able to refer clients to where those clients can obtain them. The package is simply illustrative; it would be impossible to note exactly all of the commodities needed.

Figure 2. A Comprehensive HIV/AIDS Program
Currently, three main challenges are common to HIV/AIDS programs in resource-poor settings, regardless of the nature of the epidemic: human resources, infrastructure, and resources.

The first major challenge, *the human resource crisis*, is a global issue in many resource-constrained countries and is not a new challenge. A shortage of trained medical personnel is a chronic problem that is worsened by civil conflict, failing economies, poor wages, difficult working situations, and HIV/AIDS itself. The risk is that—in high-prevalence countries—the presence of a growing AIDS epidemic makes the situation worse by requiring increased work of health personnel who might themselves be infected or who might have family members at home for whom they must care in their after-work hours. Not only are health care workers often responsible for stigmatizing patients with HIV/AIDS, but also the workers often make it hard for the patients to disclose their HIV status and to get the care and treatment they need. Care for the caregiver is a critical need for those working in HIV/AIDS service delivery.

In low-prevalence settings, there is often no shortage of medical personnel, but there is a reluctance on the part of those working to provide HIV/AIDS services. Some Eastern European countries have more medical doctors per population size than are really needed. Despite this statistic, the personnel who are needed to provide care and treatment for HIV/AIDS patients is inadequate for the demand. As discussed already, these settings consider HIV/AIDS a disease of marginalized groups. As a result, few health personnel are educated on the basic principles of HIV/AIDS prevention, care, and treatment. Some countries even have “special doctors” who do C-sections on HIV-positive women, and those who perform the C-sections get paid extra for their work.

A second major challenge in delivering HIV/AIDS services is the *lack of an adequate health infrastructure*. In some settings, the issue is as basic as a non-existent water supply. In others, those supporting the setting up of HIV counseling and testing sites have found it necessary to provide for the renovation of rooms that provide privacy for counseling sessions. Laboratory infrastructure is a key issue. Ideally, people starting on ART would have a CD4 count to assess the status of their immune system and to determine the need for ART. A viral load is a commonly ordered test in developed countries, but it is often unavailable in all but the most-sophisticated referral hospitals in the most resource-constrained settings. There is a huge challenge to keep delivery of ART up to the standards when the necessary infrastructure is absent.

The third challenge, *financial resources*, although recently in much greater supply, are often channeled and managed in ways that make it difficult to launch and sustain programs that must provide lifelong treatment to people living with HIV/AIDS. Very often, funds are not flowing in as a budget line item but are coming as a one-time donation, or as a three- to five-year program, or as a part of the country’s recurrent rather than development budget. ART delivery requires an uninterrupted drug supply; sustainability of long-term funding for ARVs is at the core of any functioning ART program.
In addition to the challenges of human resources, infrastructure, and funding, supply chain management is a critical aspect of HIV/AIDS service delivery that can “make or break” a national program. Policy makers and program managers have realized that implementing effective supply chain strategies can play an important role in minimizing challenges associated with HIV/AIDS program and ART scale-up, including:

- Risk of emerging drug resistance among patients, due to supply interruptions or procurement of poor quality drugs. Once there is drug resistance and the resistant virus is transmitted within a population, the long-term durability of the affordable first line drug regimens is lost.

- Leakage of ARV drugs from the public sector into the private sector or to other countries, thus disrupting pricing patterns, impacting forecasting and donor support and, again, increasing the likelihood of drug resistance among patients, if prescribed or used improperly.

- Increased expense to programs that already lack sufficient funds for buying and delivering drugs for essential health problems.

Therefore, paramount to the long-term success of ART programs is recognition on the part of international and national leaders of the lifelong nature of ART and therefore of the need to sustain a continuous supply of quality drugs and services, or to ensure commodity security for ARV drugs. To ensure the uninterrupted availability of all HIV/AIDS commodities at service delivery points for the medium to long term—a condition referred to as commodity security—there must be a functioning supply chain that manages the continuous flow of quality products from manufacturer to port of entry and through the in-country distribution system to the consumers. HIV/AIDS commodity security will exist when every person has reliable access to quality medicines and other essential health products whenever she or he needs them.

A robust supply chain not only delivers products, it also helps program managers determine what types of products are needed, where and when they are needed, and in what quantities they are needed. Unfortunately, competing priorities for scarce funding often result in insufficient financial, human, and technical resources for public health supply chains. Consequently, supply interruptions caused by damage, expiry, poor management, and chronic shortages are common. At this time of unprecedented expansion of HIV/AIDS programs, it is important that commodity security and supply chain issues are addressed early in the planning stages of program implementation and scale up.


## APPENDIX 1.
PREVALENCE AND TREATMENT OF HIV DISEASE SYMPTOMS

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Prevalence</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>52%</td>
<td>Paracetamol</td>
</tr>
<tr>
<td>Tiredness</td>
<td>50%</td>
<td>Multivitamins</td>
</tr>
<tr>
<td>Sleep disturbance</td>
<td>37%</td>
<td>Diazepam</td>
</tr>
<tr>
<td>Mouth sore</td>
<td>33%</td>
<td>Nystatin</td>
</tr>
<tr>
<td>Sadness</td>
<td>32%</td>
<td>Counseling</td>
</tr>
<tr>
<td>Weight loss</td>
<td>31%</td>
<td>Multivitamin</td>
</tr>
<tr>
<td>Nausea</td>
<td>28%</td>
<td>Metoclopramide</td>
</tr>
<tr>
<td>Fever</td>
<td>27%</td>
<td>Paracetamol</td>
</tr>
<tr>
<td>Cough</td>
<td>27%</td>
<td>Codeine</td>
</tr>
<tr>
<td>Depression</td>
<td>24%</td>
<td>Haloperidol</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>24%</td>
<td>Imodium</td>
</tr>
<tr>
<td>Skin problem</td>
<td>24%</td>
<td>Calamine</td>
</tr>
<tr>
<td>Pruritus</td>
<td>23%</td>
<td>Cortisone cream</td>
</tr>
<tr>
<td>Respiratory problem</td>
<td>22%</td>
<td>Antibiotics/antitusics</td>
</tr>
<tr>
<td>Vomiting</td>
<td>20%</td>
<td>Metoclopramide</td>
</tr>
</tbody>
</table>

**APPENDIX 2.**
**COMMODITIES NEEDED TO PROVIDE PMTCT SERVICES**

**COMMODITIES NEEDED TO PROVIDE PMTCT SERVICES WITHIN THE CONTEXT OF A WHO RECOMMENDED SCHEDULE FOR MOTHER AND CHILD CARE**

<table>
<thead>
<tr>
<th>When?</th>
<th>What happens in terms of intervention?</th>
<th>Implications for supply planning</th>
</tr>
</thead>
</table>
| **Antenatal visit 1**  
Between 16 and 34 weeks | • HIV/STD counselling  
• Promotion of condom use  
• HIV testing  
• Syphilis screening  
• TT Immunisation  
• Anaemia prophylaxis  
• Malaria prophylaxis as needed | Ensure access to/ availability of:  
• Condoms  
• HIV tests/consumables needed in testing  
• Syphilis test/consumables needed in testing  
• Vaccine/ consumables for administration  
• Iron and folate supplements  
• Malaria prophylaxis if needed |
| **Antenatal visit 2**  
Two weeks after the first ante-natal visit, between 18 and 36 weeks | • Syphilis treatment  
• Confirmation of HIV positive tests  
• Post-test counselling  
• Consent for ARV prophylaxis/initiation of treatment for HIV positive women if eligible  
• HIV positive women referred to support groups and services  
• Promotion of exclusive breast-feeding to all pregnant women with HIV  
• Infant feeding counselling for HIV positive mothers | Ensure access to/ availability of:  
• Antibiotics for STD treatment  
• HIV tests for confirmation and tie breakers  
• Consumables needed in testing  
• ARVs for ART as needed |
| **Antenatal visit 3**  
34-36 weeks | • Initiation of ARV treatment if eligible/prophylaxis if regimen recommended includes a pre-natal component  
• Counselling and testing of partner | Ensure access to/ availability of:  
• ARVs for ART as needed  
• ARVs for PMTCT as needed  
• HIV tests/consumables needed for testing |
| **Labour/delivery** | • Intra-partum ARV component  
• Avoidance of unnecessary invasive procedures  
• Universal precautions | Ensure access to/ availability of:  
• ARVs for PMTCT  
• Basic midwifery pack |
| **Immediate post-partum** | • Support to infant feeding (as per choice of the mother)  
• BCG, polio 0  
• Family planning, promotion of condom use | Ensure access to/ availability of:  
• Vaccines as per schedule  
• ARVs for ART as needed |
CANDIDIASIS
There are two main types of candidiasis: localised disease (of the mouth and throat, or of the vagina) and systemic disease (of the oesophagus, and disseminated disease). The mouth and throat variant (oropharyngeal candidiasis or OPC) is believed to occur at least once in the lifetime of all HIV-infected patients. Occurrence of the vaginal variant is common among healthy, adult women and is unrelated to HIV status.

While OPC is not a cause of death, it causes oral pain and makes swallowing difficult. The main symptom of OPC is creamy white legions in the mouth that can be scraped away. The symptom of oesophageal candidiasis is pain in the chest that increases with swallowing, and causes difficulty in swallowing. Disseminated candidiasis causes fever and symptoms in the organs affected by the disease. Localised disease can be treated at first with relatively inexpensive drugs such as nystatin, miconazole or clotrimazole. Systemic candidiasis requires treatment with systemic antifungal agents such as fluconazole, ketoconazole, itraconazole or amphotericin.

HERPES SIMPLEX AND HERPES ZOSTER
Herpes simplex virus infection (HSV, which causes sores around the mouth and genitals) and herpes zoster virus infection (‘zonal’ herpes or shingles) are not life-threatening but can be extremely painful. Both can cause encephalitis, which can be life threatening. Treatment with acyclovir is only marginally effective in herpes zoster but it is sometimes dramatic in HIV-associated herpes simplex with extensive ulceration. This medicine makes the herpes outbreaks last for less time and less intensity, but it does not cure genital herpes.

CRYPTOCOCCOSIS (CRYPTOCOCCAL MENINGITIS)
Cryptococcal infection is caused by a fungus that primarily infects the brain. Systemic mycoses such as cryptococcosis probably cause about 5% of all HIV-associated deaths worldwide. Cryptococcosis most often appears as meningitis and occasionally as pulmonary or disseminated disease. Cryptococcal meningitis (CRM) is the most frequent systemic fungal infection in HIV-infected persons. Without treatment, life expectancy is probably less than a month.

Cryptococcosis is relatively easy to diagnose. However, its treatment (either amphotericin B with or without flucytosine or in mild cases with oral fluconazole) and secondary chemoprophylaxis are often impossible in developing countries because of high cost and limited availability of the drugs required.

TUBERCULOSIS
Tuberculosis is a bacterial infection that primarily infects the lungs. Tuberculosis is the leading HIV-associated opportunistic disease in developing countries. For people who are dually infected with HIV and TB, the risk of developing active tuberculosis is 30-50 fold higher than for people infected with TB alone. And because Mycobacterium can spread through the air, the increase in active TB cases among dually infected people means:
- more transmission of the TB germ
- more TB carriers
- more TB in the whole population.

Tuberculosis is harder to diagnose in HIV-positive people than those who are uninfected. The diagnosis of TB is important because TB progresses faster in HIV-infected people. Also, TB in HIV-positive people is more likely to be fatal if undiagnosed or left untreated. TB occurs earlier in the course of HIV infection than other opportunistic infections.

A proper combination of anti-TB drugs achieves both prevention and cure:

- Effective treatment quickly makes the individual non-contagious. This prevents further spread of the TB germ.
- The DOTS treatment strategy recommended by WHO treats TB in HIV-infected persons as effectively as it treats those without the virus. A complete cure takes 6 to 8 months and uses a combination of antibiotics. In addition to curing the individual, it also prevents further spread of the disease to others. This is why treating infectious cases of TB has important benefits for society as whole. Isoniazid preventive therapy is recommended as a health-preserving measure for HIV-infected persons at risk of TB. TB prophylaxis has been shown to increase the survival of HIV-infected persons at risk of TB.

**CRYPTOSPORIDIOSIS AND ISOSPORIASIS**

Cryptosporidiosis (crypto) and isosporiasis are both caused by parasites. These diseases are easily spread by contaminated food or water, or by direct contact with an infected person or animal. Both crypto and isosporiasis cause diarrhoea, nausea, vomiting and stomach cramps. In people with healthy immune systems, these symptoms do not last more than about a week. However, if the immune system is damaged then they can continue for a long time. Diarrhoea can interfere with the absorption of nutrients and this can lead to serious weight loss.

To confirm diagnosis of either disease, the stool is normally checked for parasites and their eggs. There is no drug treatment that clears up or cures crypto. For isosporiasis, TMP-SMX (trimethoprim-sulfamethoxazole) is the recommended drug of choice.

**KAPOSI SARCOMA**

HIV-associated Kaposi Sarcoma causes dark blue lesions, which can occur in a variety of locations including the skin, mucous membranes, gastrointestinal tract, lungs or lymph nodes. The lesions usually appear early in the course of HIV infection. Treatment depends on the lesions’ symptoms and location. For local lesions, injection therapy with vinblastine has been used with some success. Radiotherapy can also be used, especially in hard-to-reach sites such as the inner mouth, eyes, face and soles of the feet. For severe widespread disease, systemic chemotherapy is the preferred treatment.

**LEISHMANIASIS**

Leishmaniasis is transmitted by sandflies. The most serious of its four forms is visceral leishmaniasis (VL) - also known as kala azar - which is characterised by irregular bouts of fever, substantial weight loss, swelling of the spleen and liver and anaemia (occasionally serious). Recently, there has been an increase in overlapping of VL and HIV infection. Treatment with pentavalent antimony is relatively expensive, partly because of the cost of drugs but also because hospital admission is recommended (in milder cases, trained health workers can
administer the injections or infusions at a patient’s home). Even with optimal survival time with this co-infection, average survival time is only 12 months.

**PCP**
Pneumocystis carinii pneumonia (PCP) is caused by a parasite that infects the lungs. PCP is the most frequent HIV associated opportunistic infection in industrialised countries but appears to be less frequent in Africa. The symptoms are mainly pneumonia along with fever and respiratory symptoms such as dry cough, chest pain and dyspnoea. Definitive diagnosis requires microscopy of bodily tissues or fluids.

Severe cases of PCP are initially treated with trimethoprim-sulfamethoxazole (TMP-SMX) or clindamycin and oral primaquine. Mild cases can be treated with oral TMP-SMX throughout. With both of these regimens, toxicity (notably allergic-type reactions) often requires changes in therapy. Prevention of PCP is strongly recommended for HIV-infected persons with significant immune compromise wherever PCP is a significant health problem for HIV-infected persons, and also after their first episode of PCP. Preventing and treating PCP need not be very expensive: use of non-brand generic products can reduce the cost of drugs for TMP-SMX prophylaxis.
## APPENDIX 4.
ILLUSTRATIVE LIST OF COMMODITIES FOR PALLIATIVE CARE

<table>
<thead>
<tr>
<th>Condition</th>
<th>Treatment Drug or Other Commodity</th>
</tr>
</thead>
</table>
| Pain killers | • Aspirin, paracetamol, indomethacin, and ibuprofen  
              • Codeine or dehydrocodeine  
              • Morphine, pethidine, and fentanyl |
| Diarrhea | • Loperamide or codeine  
           • Oral rehydration solutions |
| Nausea vomiting anorexia and weight loss | • Prochlorperazine for mild nausea  
                                         • Metoclopramide for nausea caused by gastro-intestinal disturbance  
                                         • Haloperidol in case of nausea caused by CNS disorder  
                                         • Systemic antifungal in case of oral and oesophageal candidiasis  
                                         • Metronidazole in case of gingivitis  
                                         • 1% gentian violet in case of mouth ulcers |
| Cough and shortness of breath | • TB treatment  
                                 • PCP treatment  
                                 • Antibiotics and fungicides for treatment of bacterial and fungal upper respiratory infections and pneumonia  
                                 • Treatment for Kaposi Sarcoma, lymphoma, and interstitial pneumonitis  
                                 • Morphine and codeine for reduction of sense of breathlessness |
| Anxiety | • Bezdiazepines |
| Fever | • Paracetamol  
       • Aspirin  
       • Ibuprofen |
| Skin problems | • Antihistamines or topical steroids  
                • Opioids for severe itching |
| Brain impairment | • Haloperidol  
                    • Chlorpromazine |
Appendix 4 (Continued)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Treatment Drug or Other Commodity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-medical items used while nursing people with late stage of AIDS</td>
<td>• Bed pan</td>
</tr>
<tr>
<td></td>
<td>• Gloves</td>
</tr>
<tr>
<td></td>
<td>• Household bleach</td>
</tr>
<tr>
<td></td>
<td>• Cutlery, bed linen</td>
</tr>
<tr>
<td></td>
<td>• Washing powder</td>
</tr>
<tr>
<td></td>
<td>• Liquid soap, betadine</td>
</tr>
<tr>
<td></td>
<td>• Buckets</td>
</tr>
</tbody>
</table>
APPENDIX 5.
SECTIONS FROM REVISED WHO CLINICAL STAGING AND IMMUNOLOGICAL CLASSIFICATION OF HIV/AIDS, PLUS CASE DEFINITIONS OF HIV AND RELATED CONDITIONS

TABLE 5.1 WHO CLINICAL CLASSIFICATION OF ESTABLISHED HIV INFECTIONS

<table>
<thead>
<tr>
<th>HIV-associated symptomatology</th>
<th>WHO Clinical Stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asymptomatic</td>
<td>1</td>
</tr>
<tr>
<td>Mild symptoms</td>
<td>2</td>
</tr>
<tr>
<td>Advanced symptoms</td>
<td>3</td>
</tr>
<tr>
<td>Severe/very advanced symptoms</td>
<td>4</td>
</tr>
</tbody>
</table>

**TABLE 5.2 PROPOSED REVISED WHO CLINICAL STAGING OF HIV/AIDS FOR ADULTS AND ADOLESCENTS WITH CONFIRMED HIV INFECTION**

<table>
<thead>
<tr>
<th>Stage</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary HIV infection</strong></td>
<td>Asymptomatic</td>
</tr>
<tr>
<td></td>
<td>Acute retroviral syndrome</td>
</tr>
<tr>
<td><strong>Clinical stage 1</strong></td>
<td>Asymptomatic</td>
</tr>
<tr>
<td></td>
<td>Persistent generalized lymphadenopathy</td>
</tr>
<tr>
<td><strong>Clinical stage 2</strong></td>
<td>Moderate unexplained weight loss (&lt;10% of presumed or measured body weight)</td>
</tr>
<tr>
<td></td>
<td>Recurrent respiratory tract infections (amnogits, tonsillits, bronchitis, otitis media, pharyngits)</td>
</tr>
<tr>
<td></td>
<td>Herpes zoster</td>
</tr>
<tr>
<td></td>
<td>Angular cheilitis</td>
</tr>
<tr>
<td></td>
<td>Recurrent oral ulceration</td>
</tr>
<tr>
<td></td>
<td>Papular pruritic eruptions</td>
</tr>
<tr>
<td></td>
<td>Seborrhoic dermatitis</td>
</tr>
<tr>
<td></td>
<td>Fungal nail infections</td>
</tr>
<tr>
<td><strong>Clinical stage 3</strong></td>
<td>Unexplained severe weight loss (&gt;10% of presumed or measured body weight)</td>
</tr>
<tr>
<td></td>
<td>Unexplained chronic diarrhea for longer than one month</td>
</tr>
<tr>
<td></td>
<td>Unexplained persistent fever (intermittent or constant for longer than one month)</td>
</tr>
<tr>
<td></td>
<td>Persistent oral candida</td>
</tr>
<tr>
<td></td>
<td>Oral hairy leukoplaikia</td>
</tr>
<tr>
<td></td>
<td>Pulmonary tuberculosis</td>
</tr>
<tr>
<td></td>
<td>Severe presumed bacterial infections (e.g. pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteremia, excluding pneumococci)</td>
</tr>
<tr>
<td></td>
<td>Acute overwhelming invasive stromatosis gravis or pneumonitis</td>
</tr>
<tr>
<td></td>
<td>Unexplained anemia (&lt;8 g/dl), neutropenia (&lt;500/mm³) and or chronic thrombocytopenia (&lt;50,000/mm³)</td>
</tr>
<tr>
<td><strong>Clinical stage 4</strong></td>
<td>HIV wasting syndrome</td>
</tr>
<tr>
<td></td>
<td>Pneumocystis carinii</td>
</tr>
<tr>
<td></td>
<td>Recurrent severe presumed bacterial pneumonia</td>
</tr>
<tr>
<td></td>
<td>Chronic herpes zoster infection (oralis orbital or anorectal if more than one month's duration or visceral at any site)</td>
</tr>
<tr>
<td></td>
<td>Osteophagical candidiasis (or candida of trachea, bronchi or lungs)</td>
</tr>
<tr>
<td></td>
<td>Extrapolumonary tuberculosis</td>
</tr>
<tr>
<td></td>
<td>Kaposis sarcoma</td>
</tr>
<tr>
<td></td>
<td>Cytomegalovirus infection (reinitis or infection of other organs)</td>
</tr>
<tr>
<td></td>
<td>Central nervous system toxoplasmosis</td>
</tr>
<tr>
<td></td>
<td>HIV encephalopathy</td>
</tr>
<tr>
<td></td>
<td>Extrapolumonary cryptococcosis including meningitis</td>
</tr>
<tr>
<td></td>
<td>Disseminated non-tuberculous mycobacteria infection</td>
</tr>
<tr>
<td></td>
<td>Progressive multifocal leukoencephalopathy</td>
</tr>
<tr>
<td></td>
<td>Classic Cryptosporidiosis</td>
</tr>
<tr>
<td></td>
<td>Chronic Isoplasma</td>
</tr>
<tr>
<td></td>
<td>Disseminated mycosis (extrapolumonary histoplasmosis, coccidioidymosis, penicilliosis)</td>
</tr>
<tr>
<td></td>
<td>Recurrent sepuculmias (including non-typhoidal salmonella)</td>
</tr>
<tr>
<td></td>
<td>Lymphoma (reticular or B cell non-Hodgkin)</td>
</tr>
<tr>
<td></td>
<td>Invasive cervical carcinoma</td>
</tr>
<tr>
<td></td>
<td>Atypical disseminated leishmania</td>
</tr>
</tbody>
</table>

*Unexplained refers to where the condition is not explained by other conditions.*

### TABLE 5.3 PROPOSED REVISED WHO CLINICAL STAGING OF HIV/AIDS FOR INFANTS AND CHILDREN WITH CONFIRMED HIV INFECTION

<table>
<thead>
<tr>
<th>Stage</th>
<th>Conditions</th>
</tr>
</thead>
</table>
| **Primary HIV infection** | Asymptomatic (extra per or post partum)  
Acute retroviral syndrome |
| **Clinical Stage 1** | Asymptomatic  
Persistent generalized lymphadenopathy |
| **Clinical Stage 2** | Unexplained persistent hepatosplenomegaly  
Papular pruritic eruptions  
Extensive wart virus infection  
Extensive molluscum contagiosum  
Recurrent oral ulcerations  
Unexplained persistent Parotid enlargement  
Lined glossal erythema  
Herpes zoster  
Recurrent or chronic upper respiratory tract infections (otitis media, otitis media, sinusitis, tonsillitis)  
Fungal nail infections |
| **Clinical Stage 3** | Moderate unexplained malnutrition not adequately responding to standard therapy  
Unexplained persistent diarrhea (14 days or more)  
Unexplained persistent fever (above 37.5°c intermittent or constant, for longer than one month)  
Persistent oral candida (after first 6–8 weeks of life)  
Oral hairy leukoplakia  
Acute necrotizing ulcerative gingivitis/periodontitis  
Lymph node TB  
Pulmonary TB  
Severe recurrent presumed bacterial pneumonia  
Symptomatic lymphoid interstitial pneumonitis  
Chronic HIV-associated lung disease including bronchiectasis  
Unexplained anaemia (<8.0 g/dl), neutropenia (<500/µl) or chronic thrombocytopenia (<50,000/µl)  
HIV-associated cardiomyopathy or HIV-associated nephropathy |
| **Clinical Stage 4** | Unexplained severe wasting, stunting or severe malnutrition not responding to standard therapy  
Pneumocystis pneumonia  
Recurrent severe presumed bacterial infections (e.g., pneumonia, pneumoniastis, bums or joints infection, meningitis, but excluding pneumoniastis)  
Chronic herpes simplex infections (ocularal or cutaneous of more than one month’s duration or visceral at any site)  
Extrapulmonary tuberculosis  
Kaposi sarcoma  
Oesophageal candidiasis (or candida of trachea, bronchi or lungs)  
Central nervous system toxoplasmosis (after one month of life)  
HIV encephalopathy  
Cytomegalovirus infection reinitis or CMV infection affecting another organ, with onset at age over 1 month  
Extrapulmonary cryptococcosis including meningitis  
Disseminated endemic mycosis (extrapulmonary histoplasmosis, coccidiodomycosis, penicilliosis)  
Chronic Cryptosporidiosis  
Chronic Isosporosis  
Disseminated non-tuberculous mycobacteria infection  
Acquired HIV associated rectal fistula  
HIV associated tumours including Cerebral or B cell non-Hodgkin lymphoma  
Progressive multifocal leukoencephalopathy |

### APPENDIX 6.
**MAJOR POTENTIAL TOXICITIES OF FIRST LINE ARV REGIMENS AND RECOMMENDED DRUG SUBSTITUTIONS**

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Toxicity</th>
<th>Drug Substitution</th>
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| **d4t/3TC/NVP** | • d4t-related neuropathy or pancreatitis  
• d4t-related lipoatrophy  
• NVP-related severe hepatotoxicity  
• NVP-related severe rash (but not life-threatening)  
• NVP-related life-threatening rash (Stevens-Johnson syndrome) | • Switch d4t ZDV  
• Switch d4t TDF or ABC  
• Switch NVP EFV  
• Switch NVP EFV  
• Switch NVP PIb |
| **ZDV/3TC/NVP** | • ZDV-related persistent GI intolerance or severe haematological toxicity  
• NVP-related severe hepatotoxicity  
• NVP-related severe rash (but not life-threatening)  
• NVP-related life-threatening rash (Stevens-Johnson syndrome) | • Switch ZDV d4t  
• Switch NVP EFV (except in pregnancy; in this situation switch to NFV, LPV/r or ABC)  
• Switch NVP EFV  
• Switch NVP PIb |
| **d4t/3TC/EFV** | • d4t-related neuropathy or pancreatitis  
• d4t-related lipoatrophy  
• EFV-related persistent CNS toxicity | • Switch d4t ZDV  
• Switch d4t TDF or ABC  
• Switch EFV NVP |
| **ZDV/3TC/EFV** | • ZDV-related persistent GI intolerance or severe haematological toxicity  
• EFV-related persistent CNS toxicity | • Switch ZDV d4t  
• Switch EFV NVP |

*Switching off d4t typically does not reverse lipoatrophy but may slow its progression. TDF and ABC can be considered as alternatives but availability is currently limited in resource-constrained settings. In the absence of TDF or ABC availability, ddI or ZDV are additional alternatives to consider.

bPI can be LPV/r or SQV/r. IDV/r or NFV can be considered as alternatives (see text).
