Supply Chain Management Implications for HIV/AIDS Policymakers and Program Managers

Introduction

The United Republic of Tanzania is rapidly scaling up its HIV/AIDS programs and is working with a number of partners that are providing funding and technical assistance. One of the government's current goals for its HIV/AIDS programs is to have more than 400,000 individuals on antiretroviral therapy (ART) in the next five years.

Mothers and their families ultimately benefit from efficient and effective supply chains.

To be eligible for ART, people living with AIDS (PLWA) must be tested through voluntary counseling and testing (VCT) and identified as being seropositive. In Tanzania, the number of individuals who must be tested is staggering; estimates are that 5 million people must be tested to enroll 100,000 new patients for treatment. To treat 400,000 will require the program to counsel and test 20 million previously untested individuals. Current capacity through existing VCT centers is less than 1 million counseling sessions per year. Based on these figures, the program will have to increase its counseling and testing capacity twentyfold or fivefold every year for the next five years.

Compounding the issue of service capacity is the inability of the program to manage significantly increased quantities of HIV test kits to test 5 million new individuals every year. A recent national stock status survey of key health commodities found that few facilities below the hospital level carried HIV test kits, and, of those that did, often there was only one type of HIV test kit in stock. At least two different types of HIV test kits are required to accurately inform a client of their HIV-positive status.

Clearly, the goal set and the constraints noted have substantial programmatic and supply chain implications. Without significant attention to the long-term security of HIV/AIDS commodities and the systems to manage them, Tanzania will not meet its stated goal, and will leave thousands of people living with HIV/AIDS without the services and commodities that they so desperately need. These challenges, not unique to Tanzania, pose a very real dilemma in many of the countries where HIV/AIDS prevention, care, support, and treatment programs are currently being scaled up.

The global community is responding to this challenge. A variety of multilateral and bilateral initiatives that have been launched in recent years offer significant resources. But most of these efforts focus primarily on improving service delivery and increasing financing for commodities to scale up HIV/AIDS interventions. Meanwhile, insufficient attention is paid to accurate forecasting, efficient procurement, and effective in-country supply chain and delivery systems, all critical for ensuring the products actually reach the clients.

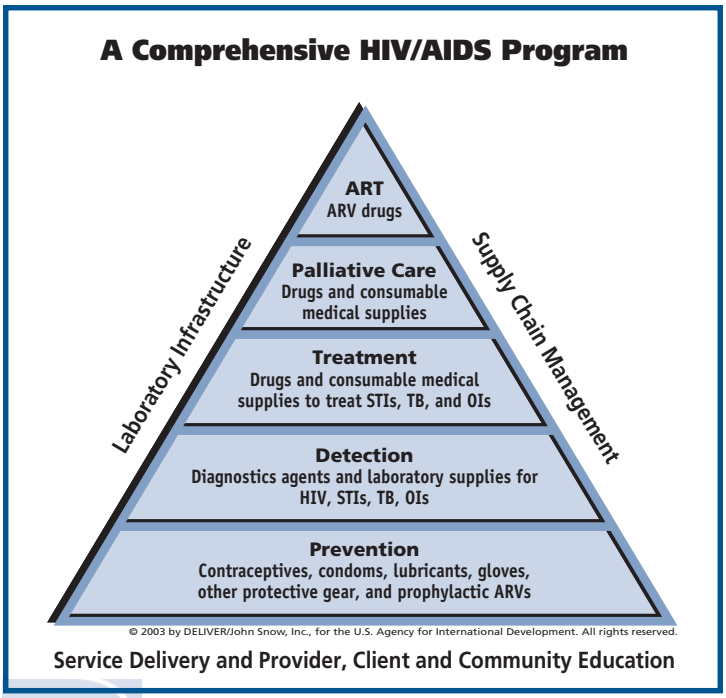
To ensure the *uninterrupted* availability of HIV/AIDS commodities at all service delivery points for the medium- to long-term—a condition referred to as *commodity security*—there must be a functioning supply chain that manages the continuous flow of quality products from manufacturer to port of entry 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, the implications of rapid scale up and capacity requirements for commodity supply chains must be considered in the earliest planning stages.

To provide comprehensive HIV/AIDS prevention, care, and treatment services, national programs must develop and maintain supply chains for more than 200 diverse products. In addition to high-value antiretroviral (ARV) drugs, these commodities include HIV tests and other laboratory reagents; medicines for treating sexually transmitted infections and opportunistic infections (OI); condoms, contraceptives, and micronutrients; and consumable laboratory and medical supplies. In most resource-poor countries it will be impossible to maintain all these products in full supply to meet all needs.

Achieving commodity security will depend on a country's capacity to accurately forecast, adequately finance, effectively procure, and consistently deliver commodities to the people who need them. This paper will briefly address some of the key implications for HIV/AIDS programs in these areas.



A comprehensive HIV/AIDS program requires secure supplies of more than 200 distinct commodities.

Forecasting HIV/AIDS Commodities

Product Selection

Selecting which commodities to procure for a national program or for a specific program can be a complicated process, but it must be done purposefully and rationally and in line with international standards.

When deciding which commodities to include for an HIV/AIDS program, program managers must put in place protocols and standards for testing and treatment, including testing protocols, standard treatment guidelines (first-, second-, and third-line treatments), dispensing protocols, and others. These protocols and standards are necessary to facilitate forecasting of commodity requirements and for tracking patient regimens and treatment failure.

Program managers should consider selecting drugs based on the World Health Organization's (WHO) standardized criteria and pre-qualified product list. Programs should use international standards to choose the safest, most efficacious, and most cost-effective products based on the epidemiological profile of their population and its HIV epidemic, patient needs, qualifications of trained staff, supply chain, and laboratory and service delivery capacity. While these criteria can be customized to meet specific country needs, standardization is important to ensure a sound public health approach to addressing the epidemic. Because the WHO pre-qualified product list is dynamic and periodically revised, programs should also plan for the possibility that a drug used in their standard treatment guidelines might be dropped from the list.

Selected products should be on the national essential medicines list and each formulation and/or the manufacturer of each product must be registered in the country. Donors and procurement agents must understand that this is a requirement to ensure that the process of drug registration is not an obstacle to procuring cost-effective quality drugs in a timely manner.

The list of commodities should be developed with a goal of reducing brand proliferation. Having multiple brands of the same commodities available to programs may complicate the supply chain management of these products and the training required for staff. This may also confuse patients, leading to non-compliance with treatment or mistrust in prevention and care commodities, and may increase program expenses.

Product Selection Considerations

Using two key HIV/AIDS commodities as examples, some additional considerations for program managers when they select HIV test kits and antiretroviral (ARV) drugs are listed below.

HIV test kits should be selected considering—

- Their purpose (e.g., blood safety, voluntary counseling and testing, preventing mother-to-child transmission, diagnostic test, sentinel surveillance), how fast results are needed, and the most up-to-date technologies.
- The sensitivity and specificity of the test kits selected, as well as shelf life, ease of use (including training requirements), and stability (consider tests that don't require refrigeration).
- Standard test kits that use the same equipment and/or operate similarly. This will help ensure that consumables are the same and can be used interchangeably, that equipment does not become obsolete, and that staff need not be retrained continuously on new equipment. Ideally, the HIV test selected will come packaged with everything required to perform the test.

ARV drugs should be selected considering—

- Preferential pricing of ARV drugs granted to developing countries, while ensuring procurement from reliable suppliers. The World Health Organization's (WHO) prequalified list should be used as the standard for selecting ARVs.
- Fixed-dose combination ARV drugs to enhance clinical outcomes (adherence) and to facilitate procurement, distribution, and dispensing to patients. However, fixed-dose combination ARV drugs may have funding considerations (e.g., donors and/or pharmaceutical companies may provide only certain drugs/combinations).
- Improved and standardized drug packaging to encourage patient adherence and facilitate proper dispensing.

Quantification

After products have been selected based on the established protocols, guidelines, national essential medicines lists, etc., national program managers can quantify commodity requirements.

The current absorptive capacity of the logistics and service delivery systems and future plans to scale up must be considered in quantifying HIV/AIDS commodity needs. The goal is to maximize coverage while reducing wastage by not over-ordering based on current capacity (i.e., consider factors such as how many products can the system manage, how many clients can be served by trained staff, how many clients can be properly tested and monitored, what is the laboratory capacity, etc.). National program managers must set criteria for programs, facilities, and/or patients to qualify to receive specific commodities while programs are scaling up (i.e., only programs and facilities that have appropriately trained staff, laboratory capacity, and secure and adequate storage areas should receive products).

An effective forecast includes the quantification of patient needs, as well as appropriate quantities of key commodities to maintain appropriate stock levels through the supply chain. A good forecast will ensure that facilities are always adequately stocked and patients always receive the life-saving commodities they need.

Quantification of HIV/AIDS commodities should be information driven, using logistics data such as current consumption, stock currently available in country, and losses and wastage, when possible. It is important to design an information system that will provide reports to decision makers routinely and reliably, so the data can be used for quantifying needs and adjusting forecasts and procurement plans, as needed. This system must be set up immediately at start-up so the program can transition rapidly from assumption-based to information-driven forecasts.

As HIV/AIDS programs are set up or prepare for scaling up, forecasts need to be monitored frequently, and the procurement and shipment process must be very flexible. The procurement system and supply chain must be able to adapt quickly to unpredictable changes in client uptake of services, changes in testing and treatment protocols, and rapid scale up. Consolidating quantification of products across programs can streamline work and, based on larger orders, can result in lower unit prices.

The decision of whether to prepare short-term or long-term projections (or both) also has implications for procurement, financing, and manufacturing. Short-term projections are necessary and more reliable because of the lack of accurate consumption data and uncertainties around uptake and regimen changes. These projections give program managers more flexibility in changing forecasts and procurements as regimens change and new products come on the market. However, long-term projections

are preferable for manufacturers to plan production, adjust prices, and plan shipments. Long-term projections are also useful for advocacy for financing and government planning to fill funding gaps, conduct procurement planning, and minimize stockouts.

Financing HIV/AIDS Commodities

Increased knowledge about the detrimental health, societal, economic, and social impact of the HIV/AIDS epidemic by the global community has drastically increased funding for HIV/AIDS programs. While this provides significant opportunities for countries to expand their prevention, care, treatment, and support activities, there are a number of key supply chain implications that must be weighed to ensure that the resources are maximized and the greatest number of people can reliably access the HIV/AIDS services and products they need.

The cost of managing the supply chain for key HIV/ AIDS commodities must be covered. Supply chain management functions, such as storage, distribution, and information systems, are rarely incorporated in national budgets or commodity donations. Without financial investment in supply chain management, valuable commodities may not be distributed to the service delivery sites or could be lost due to theft or unnecessary wastage.

To prevent interruptions in the supply of essential HIV/ AIDS commodities as a result of funding gaps, multiple sources of financing must be coordinated. Different funding and procurement cycles of different donors affect product availability; for example, a one-month delay in the release of funds can translate into several months of product stockout or could result in a stockout of one drug of a three drug regimen.

When ARV drug packaging and/or formulation cannot be standardized between financing and procurement mechanisms, the provision of the different ARV drug formulations should be segmented through different fees, service channels, or geographic locations. This will minimize client confusion and help promote adherence by guaranteeing that the drugs clients receive are consistent from month to month. Kenya provides a good example of this (see box above).

To ensure long-term financing for ARV drugs and other HIV/AIDS commodities, countries need to work with their funding partners, while they increase their own resource contribution. The provision of ARV drugs is a life-long commitment to clients. Although the immediate goal of many programs is to enroll as many patients as possible on ART, planning to sustain long-term funding of the ARV drugs should start early in program implementation.

Additional funding for ARV drugs can be generated through alternative financing mechanisms, including

Kenya's Segmented Procurement

The Government of Kenya is planning to spend its own money and the Global Fund's money on standard first-line fixed-dose combinations (FDCs), which are only available through generic manufacturers. The Emergency Plan, at least initially, will only support originator products, and will supplement the Government of Kenya's (GOK) contributions by purchasing drugs for non-standard first-line and second-line treatment (currently only available in branded form). There are also plans to segment the country, so when the Emergency Plan does purchase single drugs for the standard first-line regimen, it will consistently supply selected sites, while GOK supplies others. This will ensure that patients at each site receive the same drugs (FDC or singles) month after month.

Cost Sharing in Uganda

In Uganda, the Ministry of Health (MOH) has outsourced the storage, distribution, and part of the logisitics management information system (LMIS) functions to the National Medical Stores (NMS). NMS negotiates a fee with the MOH or donor for a percentage of the commodity value, depending on the range of services provided. As an example, NMS charges 10 percent of the value of essential medicines for primary health care procured by the Government and DANIDA for storage, distribution to the district level, and collection of bimonthly orders. In contrast, commodities procured through the World Bank's Multi Country AIDS Program, which are higher-value HIV/AIDS commodities, are only assessed at a 6.5 percent fee for storage and distribution. Other countries, such as Kenya, include technical assistance and funding to strengthen their supply chains in their Global Fund proposals.

employer-funded services, national health insurance, community health funds, health savings and loan plans, and client fees, while ensuring access regardless of ability to pay. These alternative funding mechanisms can help ensure long-term, sustainable financing for commodities and supply chain functions.

Procuring HIV/AIDS Commodities

Procurement considerations are closely related to those mentioned in finance. Procurement complications increase as the number of funding sources increase, because, in general, each funding source is affiliated with a different procurement mechanism. These complications can lead to the purchase of non-registered products, delays in payment, long lead times prior to delivery, and large customs and demurrage charges, all ultimately affecting product availability at the service delivery level. Managing these complications requires careful coordination among all the funding agencies, including the government, donors, and pharmaceutical companies.

As countries expand their HIV/AIDS programs, they are exploring options to make procurement more effective and more responsive to donor requirements and the evolving commodity needs.

For selected commodities, such as ARV drugs, governments must determine whether they will oversee/manage procurement for programs across different sectors or just for the public sector program. Benefits of procuring ARV drugs for all the sectors include enhanced control over the drug supply (thus minimizing importation of sub-standard drugs), potential volume savings, improved coordination, and better reporting from the other programs.

Tips for Efficient Procurement

The procurement process should be as responsive and uncomplicated as possible through actions such as—

- Using pre-qualified suppliers (e.g., WHO pre-qualified suppliers).
- Lowering the cost of HIV/AIDS commodities through preferential pricing from originator pharmaceutical companies, purchasing generic drugs, or bulk purchasing using either pooled procurement or negotiation.
- Fast tracking drug registration for HIV/AIDS commodities, such as accepting regulatory approval from a WHO-certified country (most European countries, Canada, U.S.).
- Securing required waivers to deviate from current government procurement system to meet donor requirements or to rapidly procure HIV/AIDS commodities.

All these actions, taken in advance, can ensure product availability through the correct and timely procurement of HIV/AIDS commodities.

Contract Mechanisms for Procurement

Examples of procurement or contracting mechanisms that countries and programs are exploring to accommodate special characteristics of HIV/AIDS commodities include—

- Framework contracts or long-term agreements in which the buyer agrees to purchase a certain amount of the product and the supplier agrees to produce it at a reduced price. On a global level, one example is the Clinton Foundation, which has negotiated rates with generic ARV drug manufacturers, suppliers of raw materials for ARVs, and manufacturers of HIV test kits and other laboratory reagents for HIV- and AIDS-related tests. The negotiated rates are lower than the published market rates, and countries can access them by signing memorandums of understanding with the foundation.
- Contracts that allow multiple shipments per year for products with a short shelf life or that require cold chain. This kind of contract is critical for HIV test kits that have a shelf life of less than 15 months and could expire in large quantities if countries receive the entire year's shipment at one time.
- Contracts that allow renegotiation of price if the international prices decline more than a certain percentage.
- Contracts that allow multiple payments. This might require a previously well-established relationship between the purchaser and the manufacturer or supplier. It would be a useful strategy in countries that receive money from the Global Fund for commodity purchases, because these monies are released several times a year.

The disadvantages include the increased burden on already strained government resources and the lack of alternate sources of supply for clients when there is a national level stockout.

An appropriate procurement method should be selected based on market availability, critical delivery dates, and the nature of the product being procured. Procurement contracts should be negotiated to be flexible and to maximize cost savings and ensure timely delivery. In many cases, this may require sole source/direct contracting or restricted international bidding, as there is a limited number of suppliers for many of the HIV/AIDS commodities.

Procurement systems should be flexible to respond to the evolving epidemic and rapid scale up. While government procurement systems worldwide tend to be bureaucratic to ensure the accountable spending of public funds, this limits their flexibility. Without flexibility, countries may not be able to adapt quickly to donor procurement regulations or ensure that alternative therapies are available for those who experience side effects or resistance to first-line regimes.

Different procurement mechanisms must be coordinated and reconciled to ensure standardization among products, as well as timely and complimentary commodity delivery. This is especially important for HIV tests and ARV drugs. Most HIV testing algorithms require two tests to confirm a client's HIV positive status; if only one test is available at a given time, or if both tests are available but there are no consumables, the quality of the testing service is severely compromised. Similarly with ARV drugs, when FDCs cannot be used, three individual drugs from three separate manufacturers must be available at the same time to provide a single ART regimen. If one of the drugs is not available, the entire regimen is often unusable.

A coordinated procurement process leads to timely commodity distribution and a satisfied customer.

A commodity tracking system that provides a full picture of all HIV/AIDS commodity procurements (regardless of source) is critical, beginning with tendering and moving through contract negotiation, order and shipment status, port clearance, and delivery to the central warehouse. This will help monitor procurement status and highlight potential problems. It can also monitor the different products that must be available at the same time (i.e., the single dose pills that make up a regimen or test kits and the required lab reagents) to ensure that they are procured in a coordinated process.

The quality of the products procured must be closely monitored. Because of the high value of HIV/AIDS commodities, the potential for counterfeit or poor manufacturing practices exists. Unless countries ensure the quality of the products procured—beginning with using pre-qualified suppliers through post-market surveillance—they risk spending funds on ineffective products.

Distributing HIV/AIDS Commodities

It is imperative that selected HIV/AIDS commodities, such as HIV test kits, ARV drugs, and specialized OI drugs, are kept in full supply, because they often mean the difference between life and death for many clients. In addition, if stockouts occur, they could result in drug resistance for clients on ART and other essential medicines, and programs risk losing clients if they are unable to provide reliable services and commodities to clients who sometimes take great personal and social risks when they seek services.

For sustainability, it is critical that programs focus on building capacity (human and structural) in the distribution of these high-value commodities. It may take years to stabilize supply chain operations for HIV/AIDS commodities because of the process of scaling up to national coverage, future fluctuations in demand, and potential switching between different and new regimens as new drugs are developed.

It may be necessary, for overall system efficiency, to set up a parallel distribution system in the short-term, separate from other health commodities, but set up in such a way that

all or some functions could be integrated in the long-term. Because of the significant public health consequences of stockouts and the uncertainties around uptake rates, initial orders may need to be small because of the cost and sensitivity of many HIV/AIDS commodities, and distribution may need to be more frequent to meet demand. Countries may also have to coordinate distribution of HIV/AIDS commodities between different programs (e.g., MOH, nongovernmental organizations, employer-based, and commercial outlets), at least in the short-term.

Managers will have to decide to what level of the health system or to which specific facilities the commodities will need to be distributed (e.g., referral hospitals or community health centers, urban or rural health facilities, etc.). As programs scale up, initially, certain HIV/AIDS services—VCT, PMTCT, and ART—may only be provided at specific sites at provincial or district levels, not at all health facilities. All the scenarios have implications for the supply chain, affecting storage capacity, the transportation system for each commodity, and the collection of logistics data for decision making.

One key requirement for site selection for distributing HIV/AIDS commodities is the presence of trained staff and equipment to offer a complete package of services, in addition to onsite or referral to laboratory services with capacity for testing and monitoring. This question of which facilities and, therefore, which sub-populations will have access to these services and commodities raises important questions around equity of access by the population. Policymakers and program managers will have to set criteria for facilities to qualify to receive many key HIV/AIDS commodities that require special skills and infrastructure, such as HIV tests and ARV drugs.

Parallel transportation systems and storage areas that are secure and appropriate may be necessary in the short-term, but should be set up so that they can be integrated with other health services in the long-term. Because of the high value of many HIV/AIDS commodities, program managers must ensure secure transportation between sites and secure storage areas to prevent theft and diversion to the black market. It will be necessary to maintain the cold chain for some HIV/AIDS commodities and ensure appropriate storage conditions on a consistent basis. It is important to monitor expiry dates closely because of the short shelf life of many HIV/AIDS commodities. Although HIV/AIDS programs need to respond rapidly to the growing crisis, many health experts fear that shortsightedness will result in systems that are not sustainable.

Shortening the Pipeline

In Kenya and Uganda, streamlined supply chains have been set up for distribution; products go straight from the central warehouse to the service site. This shorter pipeline means that products move faster through the supply chain to the service delivery point. With an improved process, the products arrive at the service delivery point faster and, therefore, have more time left before their expiry date.

Supply chains that manage HIV/AIDS commodities can only function effectively by using logistics data for daily operations, as well as for longer term strategic planning. HIV/AIDS programs will need to set up a logistics management information system (LMIS) for ordering commodities; for reporting use, wastage, and stock levels; and for managing money and recording the use of fees collected. These data are crucial for accountability and decision making (i.e., ordering and resupply, forecasting, scaling up services). An information system will also be important for reporting service statistics, patient monitoring, and estimating the absorptive capacity of the system for accepting new patients.

The LMIS for these commodities may need to be separate in the short-term for rapid scale up, but integrated with other health programs for long-term sustainability and to reduce duplication and reporting requirements on already over-burdened staff and/or data collectors. Regardless of the information system selected, programs need a logistics data collection system that is user friendly and that can provide timely and accurate data. Program managers at all levels must analyze the data collected and give feedback to health care providers and staff

When selecting sites for HIV/AIDS commodity distribution, short- and long-term system requirements must be considered.

to improve commodity and facility management and to ensure continuous product availability.

Program managers should carry out periodic evaluations to gauge security, quality of reporting and storage, and quality of client services and counseling. To ensure program success, it is important to use frequent supervision to incorporate quality controls at all levels of the program for both products and services. While managers are supervising, they can also provide on-the-job training; updated information; and training on new technologies, products, and equipment.

Program managers should consider putting a mechanism in place for facilities to place emergency orders of key commodities, especially ARV drugs. ART programs must have a zero stockout policy, because the risks of stockouts carry such important public health implications. There is always a trade-off between holding higher buffer stock levels and greatly minimizing the risks of stockouts and holding lower buffer stocks but increasing the chances of stockouts. Keeping high buffer stocks of ARV drugs is costly, and the added cost may mean that fewer patients are treated. However, more stock means that emergency orders are needed less frequently, which cuts costs because emergency orders require dedicated resources and transport to fill the order. In either case, emergency order procedures should be developed, maintained, and followed at all sites.

Conclusion

HIV/AIDS commodity security—or a reliable supply of key commodities—is essential to the success of HIV/AIDS prevention, care, and treatment programs. Commodity security depends on a country's capacity to accurately forecast, adequately finance, effectively procure, and consistently deliver essential HIV/AIDS commodities to the people who need them. Investing in a commodity security approach for ensuring continuous product availability for HIV/AIDS programs is cost effective, improves program impact, and saves lives. Success is possible when commodity security is addressed early in the planning stages of program implementation and scale up.

Tanzania has recognized the importance of commodity security for ensuring continuous product availability and long-term achievement of HIV/AIDS program goals. The Ministry of Health (MOH) and its donor partners are starting the process to address commodity security for critical products that are currently stocked out; they will then move on to planning for the medium-term. Simultaneously, the MOH and the Medical Stores Department, with support from key donors, is investing in significant improvements to the supply chain to enhance product availability for all essential health commodities in Tanzania. The government realizes that without HIV/AIDS commodity security, achieving 400,000 patients on ART will be a distant goal.

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