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Guidelines for Managing the HIV/AIDS Supply Chain

DELIVER
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December 2005

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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.

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Abstract
Comprehensive national HIV/AIDS programs are relative newcomers to public health programs in resource poor 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 Foundation's 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 poor 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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Contents

Acronyms

ACP	AIDS control program
AD	auto-destruct
AD	auto-disable
AFR	Bureau for Africa (USAID)
AIC	AIDS Information Centre
AIDS	acquired immune deficiency syndrome
AIM	USAID-funded district based AIDS project
ALT/AST	Alanine Aminotransferase/Asparate Aminotransferase
AMC	average monthly consumption
AMREF	African Medical and Research Foundation
ANC	antenatal care
API	active pharmaceutical ingredients
ART	antiretroviral therapy
ARVs	antiretrovirals
AZT	zidovudine (also ZDV)
BCG	Bacillus Calmette-Guérin (vaccine for tuberculosis)
BI	Boehringer Ingelheim
BTS	National Blood Transfusion Service of Zimbabwe
BV	bacterial vaginosis
CA	cooperating agency
CAFS	Center for African Family Studies
CBD	community-based distribution
CCID	cell culture ineffective dose
CD/ROM	compact disk/read-only memory
CDC	Centers for Disease Control and Prevention (Atlanta, Georgia)
CDC/GAP	Centers for Disease Control and Prevention/Global AIDS Program

CDD	Control of Diarrheal Diseases
CHPS	community-based health planning and services
CHW	community health worker
CI	composite indicators
CIDA	Canadian International Development Agency
CMS	central medical stores
COMESA	Common Market of East and South African nations
COPE	client-oriented, provider-efficient
CPI	continuous physical inventory
CSW	commercial sex worker
DACC	District AIDS Control Coordinator (Tanzania)
DANIDA	Danish International Development Agency
DAR	daily activity register
DDHS	Directors District Health Services
DDS	drug and dietary supplements
DFID	Department for International Development (UK)
DHCB	District Health Management Boards
DHMT	District Health Management Teams
DHS	Demographic and Health Survey
DHT	District Health Team
DOTS	directly observed treatment short-course
DPT	diphtheria, pertussis, tetanus
DRP	distribution resource planning
DTLS	District Tuberculosis and Leprosy Supervisor
ECOWAS	Economic Community of West African States.(15 states)
ED	essential drugs (essential medicines preferred)
EDD	Essential Drug Distribution
EDL	Essential Drug List (also see National Essential Drug List)
EDLIZ	Essential Drugs List for Zimbabwe

EDP	Essential Drug Program (Tanzania)
EIA	enzyme immunoassay
ELISA	enzyme linked immunosorbent assay
EOP	emergency order point
EU	European Union
FCT	Federal Capitol Territory (Nigeria)
FBO	faith-based organization
FDA	Federal Drug Administration
FDC	fixed-dose combination
FEFO	first-to-expire, first-out (warehouse management)
FHA	Family Health and AIDS Program
FHI	Family Health International
FIFO	first-in, first-out
FISH	first-in, still-here
FMOH	Federal Ministry of Health (Nigeria)
FOCUS	condom forecasting methodology
FP	family planning
FY	fiscal year
GACPAT	IgG antibody captured particle adherence test
GAVI	Global Alliance for Vaccines and Immunization
GDF	Global Drug Facility of the Stop TB Partnership
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GHANAPA	Ghana Population and AIDS Program
cGMP	current good manufacturing practice
GMP	good manufacturing practice
GMS	Government Medical Stores
GOG	Government of Ghana
GOZ	Government of Zimbabwe
GPA	Global Project on AIDS

GRMA	Ghana Registered Midwives Association
GSA	General Services Administration
GSMF	Ghana Social Marketing Foundation
GTZ	*Deutsche Gesellschaft fur Technische Zusammenarbeit* (German international development agency)
HAART	highly active anti-retroviral therapy
HAQOCI	HIV/AIDS Quality of Care Initiative
HBC	home-based care
HBV	hepatitis B virus
HCV	hepatitis C virus
Hib	*(Haemophilus* influenza type b conjugate vaccine)
HIPC	highly indebted poor countries (see PRSP)
HIV	human immunodeficiency virus
HIV/AIDS	see HIV and AIDS
HMIS	health management information system
HSD	health sub-district
HSR	health sector reform
HSSP	Health Sector Strategic Plan (Kenya)
HSSP	Health Sector Strategic Plan (Uganda)
HSV	herpes simplex virus
ICS	inventory control system
ID	intradermal
IDA	iron deficiency anemia
IDA	International Dispensary Association
IDD	iodine deficiency disorder
IDM	Institute for Development Management (Tanzania)
IEC	information, education, and communication
IM	intramuscular
IMCI	Integrated Management of Childhood Illness

IMR	infant mortality rate
IPPA	International Partnership Against AIDS (Africa)
IPPF	International Planned Parenthood Federation
IPT	intermittent preventive treatment
ISO	International Standards Organization
IT	information technology
IV	issues voucher (or intravenous)
JSI	John Snow, Inc.
KDHS	Kenya Demographic and Health Survey
KEMSA	Kenya Medical Supplies Agency
KEPI	Kenya Expanded Programme for Immunization
KfW	*Kreditanstalt für Wiederaufbau* (German funding agency for international development)
LIAT	Logistics Indicators Assessment Tool
LIFO	last-in, first-out
LMIS	logistics management information system
LMU	logistics management unit
LSAT	Logistics System Assessment Tool
MAC	Matebeleland AIDS Council
MAP	Multi Country AIDS Program
MAQ	maximizing access and quality
max-min	maximum and minimum supply
MCAZ	Medicines Control Authority of Zimbabwe
MCH	Maternal and Child Health
MCH/FP	Maternal and Child Health/Family Planning
MDR/TB	multi drug resistance/TB
MIS	management information system
MOH	Ministry of Health
MOPH	Ministry of Public Health

MOS	months of supply
MOSH	months of stock on hand
MOU	memorandum of understanding
MSCU	Medical Supplies Coordinating Unit (Kenya)
MSD	medical stores department
MSF	*Medecines Sans Frontières*
MSM	men having sex with men
MTCT	mother-to-child transmission (used by researchers and funders)
MVA	manual vacuum aspiration
MWRA	married women of reproductive age
NAC	National AIDS Council
NACP	National AIDS Control Program
NACP	National AIDS Control Programme (Tanzania)
NAFT	National AIDS Trust Fund
NatPharm	National Pharmaceutical Corporation
NDC	national distribution center
NDOH	South Africa Department of Health
NEDL	National Essential Drug List (also see Essential Drug List, NEML)
NEML	National Essential Medicines List (preferred)
NETA	National Emergency Taskforce on AIDS
NGO	nongovernmental organization
NHLS	National Health Laboratory Services
NID	national immunization day
NNRTI	non-nucleoside reverse transcriptase inhibitors
NPHLS	National Public Health Laboratory Services (Kenya)
NRTI	nucleoside analogue reverse transcriptase inhibitor
NTCP	National Tuberculosis Control Program
NtRTI	nucleotide analogue reverse transcriptase inhibitors
NVP	nevirapine

O&P	ova and parasites
OC	oesophageal candidiasis
OGAC	Office of the Global AIDS Coordinator
OI	opportunistic infection
OJT	on-the-job training
OPV	oral polio vaccine
OR	operations research
OVC	orphans and vulnerable children
PATH	Program for Appropriate Technology in Health
PCR	polymerase chain reaction
PEP	post exposure prophylaxis
PEPFAR	President's Emergency Plan for HIV/AIDS Relief
PHC	primary health care
PHMT	Provincial Health Management Team
PHNC	Population, Health and Nutrition Center
PI	protease inhibitor
PID	pelvic inflammatory disease
PLWH/A	people living with HIV/AIDS
PMCT	preventing mother-to-child transmission
PMTCT and PPTCT	preventing PMCT or PTCT
PMTCT+	beyond preventing MTCT, considering the family
PNA	National Procurement Pharmacy
PSA	procurement services agent
PSI	Population Services International
PTB	pulmonary tuberculosis
PTCT	parent-to-child transmission (used by community advocates)
PVO	private voluntary organization
Q	quarter
QA	quality assurance

RACC	Regional AIDS Control Coordinator
RBC	red blood cell
RBM	Roll Back Malaria
RCCO	Regional Cold Chain Operator (Tanzania)
RDT	rapid diagnostic test
RLA	regional logistics advisor
RMO	regional medical officer
RO	regional office
RPR	rapid plasma reagin
RTD	rapid test device
SCMS	Supply Chain Management System
SDP	service delivery point
SIDA	Swedish International Development Cooperation Agency
SKU	stockkeeping unit
SOH	stock-on-hand
SOW	scope of work
SPARHCS	Strategic Pathway to Reproductive Health Commodity Security
STAFH	Support to AIDS and Family Health project (Malawi)
STD	sexually transmitted disease
STGs	standard treatment guidelines
STI	sexually transmitted infection
SWAp	sector wide approach
SWOT	strengths, weaknesses, opportunities, and threats
TA	technical assistance
TAI	treatment after interruption
TAP	Tanzania AIDS Project
TAR	technical assistance record or report (FPLM)
TASO	The AIDS Support Organization
TB	tuberculosis

TBA	traditional birth attendant
TOT	training of trainers
TPHA	Treponema Pallidum Hemagglutination Assay
TRIPS	Trade Related Aspects of Intellectual Property Rights
TT	tetanus toxoid
U.S.	United States
U.S.$	currency (dollars) in the United States
UN	United Nations
UNAIDS	United Nations Programme on HIV/AIDS
UNDP	United Nations Development Program
UNEPI	Uganda National Expanded Program for Immunization
UNFPA	United Nations Population Fund
UNHCR	United Nations High Commission for Refugees
UNICEF	United Nations Children's Fund
UNIPAC	United Nations Packing and Assembly Center
UPMA	Uganda Private Midwives Association
URC	University Research Corporation
USAID	United States Agency for International Development
USG	U.S. Government
UTI	urinary tract infection
V&B	Department of Vaccines and Biologicals
VCT	voluntary counseling and testing (HIV/AIDS)
VDRL	venereal disease research laboratory test
VL	viral load
WAHO	West Africa Health Organisation
WARO	West African Regional Office
WB	World Bank
WBD	workplace-based distribution/distributor (Ghana)
WHO	World Health Organization (Geneva, Switzerland)

WHO/GPA	World Health Organization/Global Programme on AIDS
WRA	women of reproductive age
WTO	World Trade Organization
WTO-TRIPS	World Trade Organization-Trade-Related Aspects of Intellectual Property Rights
WWW	World Wide Web
ZACH	Zimbabwe Association of Church-Related Hospitals
ZDV	zidovudine (also AZT)
ZEDAP	Zimbabwe Essential Drugs Action Program
ZINQAP	Zimbabwe National Quality Assurance Program
ZNFPC	Zimbabwe National Family Planning Council

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HIV/AIDS Commodity Security

A Framework for Strategic Planning

December 2005

DELIVER
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Contents

Abbreviations and Acronyms

ART	antiretroviral therapy
ARV	antiretroviral
IEC	information, education, and communication
OI	opportunistic infection
PEP	post-exposure prophylaxis
PMTCT	prevention of mother-to-child transmission
QA	quality assurance
STI	sexually transmitted infection
TB	tuberculosis
VCT	voluntary counseling and testing

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 antiretorviral (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 surveil-

Figure 1.
HIV/AIDS Commodity Security Framework

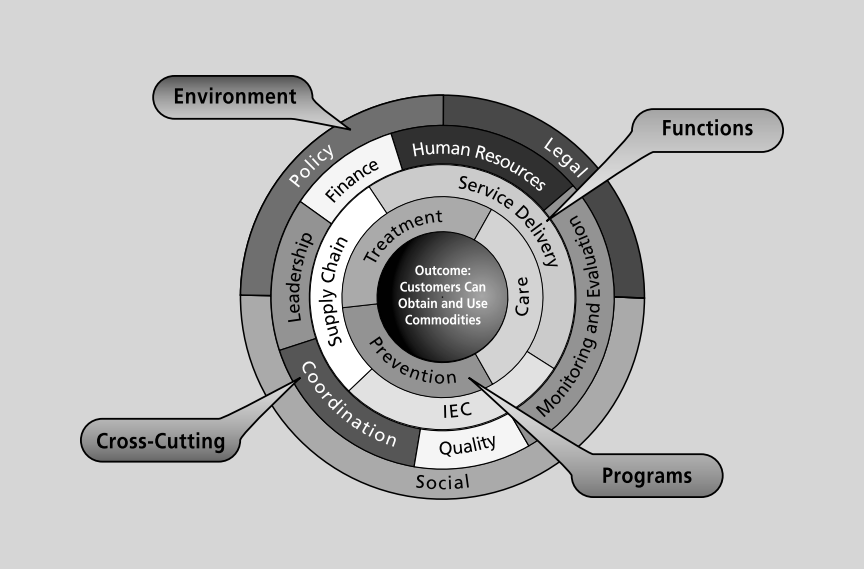
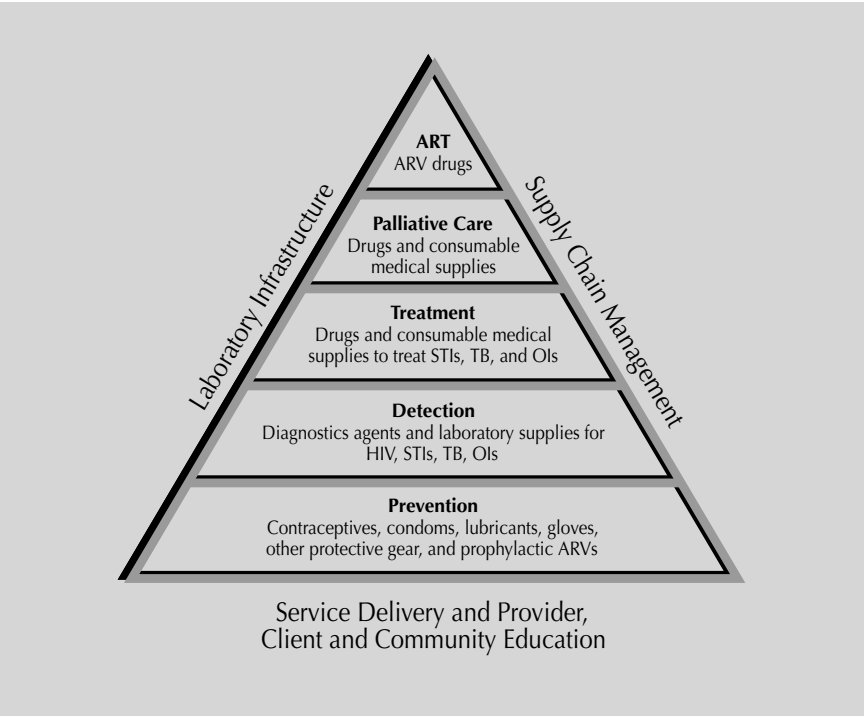


Figure 2.
A Comprehensive HIV/AIDS Program

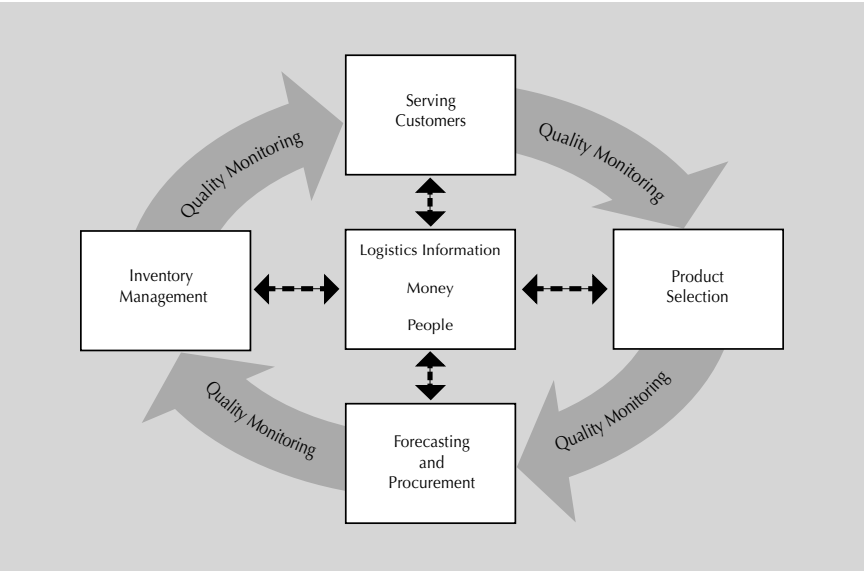


lance, and condom distribution. Treatment programs could include ART and PEP, while care will include palliative care and tuberculosis (TB) treatment. Note that many of these programs will overlap the general categories; OI treatment, for example, can be considered as both prevention and care. These 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.

Figure 1.
Logistics Cycle



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).

Box 2.
Ensuring Commodity Security in Malawi

Initially, the ART program in Malawi focused on providing a very limited number of first-line regimens to patients. Most facilities were initially restricted to one or two first-line regimens mainly supplied as fixed-dose combinations. As the program scaled up and Malawi began to provide more second-line and alternative regimens to address the needs of those patients experiencing treatment failure, the realization came that laboratory services did not have a constant supply of reagents, kits, and consumables or the equipment needed to fully support treatment—for example, equipment for detecting treatment failure). HIV/AIDS commodity security is not just about providing a range of first- and second-line treatment regimens for ART but also about strengthening laboratory systems to ensure commodity security for laboratory services, as Malawi is now undertaking to do.

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 epide-

miological 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 secu-

rity 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.

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 oversupplies 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 polices 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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Supply Chain Management of Antiretroviral Drugs

Considerations for Initiating and Expanding National Supply Chains

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DELIVER
No Product? No Program. Logistics for Health

Contents

Abbreviations and Acronyms

AIDS	acquired immunodeficiency syndrome
ART	antiretroviral therapy
ARV	antiretroviral
FBO	faith-based organizations
FDC	fixed-dose combination
HIV	human immunodeficiency virus
HMIS	health management information system
JSI	John Snow, Inc.
LMIS	logistics management information system
NEML	National Essential Medicines List
NGO	nongovernmental organization
OI	opportunistic infection
PLWHA	people living with HIV/AIDS
PMTCT	prevention of mother-to-child transmission
PVO	private voluntary organization
QA	quality assurance
STGs	standard treatment guidelines
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
WHO	World Health Organization

Preface

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

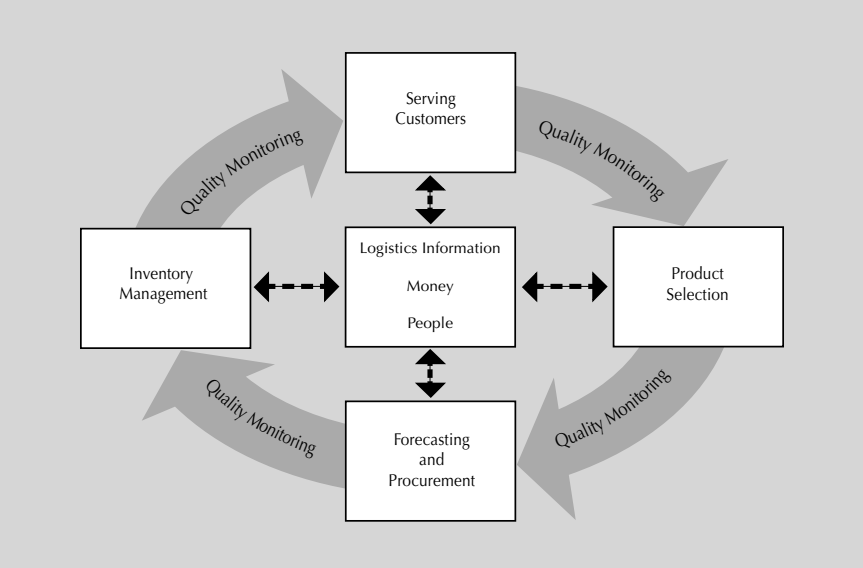
Supply chain management of essential health commodities, including high-value medicines like antiretroviral (ARV) drugs, involves a series of activities to guarantee the continuous flow of products from the point of manufacture to the point where they are used by consumers. The supply chain or its functions 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

Figure 1.
Logistics Cycle



- 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 forecast-

ing 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 I

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 implications 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

Box 1.
Challenges in Implementing STGs for ART

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.

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 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.

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.

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 improving existing capacity. Also, assessments should consider the facility capacity in the multiple areas required for providing ART service.

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 grow-

ing 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 commmittees 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.

Section III

Quantification and Forecasting

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) 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.

Section IV

Logistics Management Information Systems

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 inter-

mittent 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

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.

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.

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.

Section V

Inventory Management

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 available 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).

Box 5.
Adapting Inventory Control Mechanims 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.

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 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).

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.

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 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 developing pricing policies. For example, a major issue to consider is whether a large population of patients currently on treatment will move from paying for drugs and services through the private sector to accessing those medications free or at highly subsidized costs through the public sector after free drugs become available. The benefits of higher adherence rates associated with free treatment should be weighed against considerations for long-term financing.

The policy related to pricing will also affect dispensing of drugs, and clear guidelines need either to come from the national level or to be developed at the regional or site level to address drug dispensing in a cost-recovery environment. For example, if patients can afford to pay for only a portion of the month's supply, what are the guidelines for dispensers to follow if a prescription is required for each resupply and if those funds are to be used toward financing the facility's following month's drug purchases. Similarly, if patients are required to come for monthly appointments and if the facility receives only a one-month supply every month, but patients request drugs be dispensed for two or three months because of the cost of transportation, what procedures should dispensers follow? Guidelines and tools should also exist to help providers use the cost-recovery monies appropriately, whether they are to be used for purchasing new supplies, for supplementing the drug supply, for assisting the facility to enroll new patients on treatment, or just for assisting with facility-related costs.

Ensuring a regular flow of finances for ongoing procurement of ARV drugs after patients have been enrolled for ART will be critical to ensuring a consistent flow of those drugs into the country and thus down to the clients. Setting up guidelines for financing mechanisms at all implementing ART sites is also critical to ensure that sites do not stock out of drugs because of a lack of funds or interruptions in financing sources, especially if the resupply depends on local purchases. In such cases, clear guidelines for managing funds for purchasing ARV drugs at local and national levels should be developed, especially if drugs will be partially subsidized to patients. In the latter example, guidelines should be established to determine how money will be collected and channeled toward the repurchase of ARV drugs.

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.

Section VIII

Cross-Cutting Issues

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 nation-

al 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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USAID
FROM THE AMERICAN PEOPLE

Guide for Quantifying HIV Test Requirements

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DELIVER
No Product? No Program. Logistics for Health

Contents

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- MOH, National AIDS Control Program (NACP)
- MOH, Diagnostic Services
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Kenya

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Uganda

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- CDC/Uganda
- Crown Agents
- DDHS Pallisa District
- Uganda Health Sector Strategic Plan (UHSSP)
- Joint Medical Stores (JMS)
- Makasero Blood Transfusion Unit
- MOH, Infection Control
- MOH, Malaria Program
- MOH, Pharmacy
- MOH, STD/ACP
- MOH, TB/Leprosy
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1. Introduction

A. Expansion of HIV/AIDS Programs

Many countries in the developing world are expanding the range and quality of HIV/AIDS prevention, care, support, and treatment interventions in order to contain and reduce the spread of the epidemic. To facilitate the expansion of services, governments, donors, and other development partners are dedicating a greater proportion of development resources to scale-up HIV/AIDS-related interventions. The Global Fund for AIDS, Tuberculosis and Malaria (GFATM), the World Bank Multi-Sectoral AIDS Project (MAP) initiative, the U.S. Centers for Disease Control and Prevention Global AIDS Program (CDC/GAP), and the U.S Agency for International Development (USAID) IMPACT project are examples of new, significant resource pools available to HIV/AIDS programs.

The range and quality of services being offered are dependent in part on the availability of HIV/AIDS commodities. The full range of commodities consists of more than 120 products, including—

- condoms for STI/HIV prevention
- essential drugs for treatment of sexually transmitted infection (STI)
- HIV tests
- essential drugs for opportunistic infection (OI) and palliative care
- antiretroviral drugs
- contraceptives.

With the increased volume of commodities, and the need to ensure a consistent and reliable supply to customers, successful programs must be able to—

- Quantify their commodity needs.
- Obligate or orchestrate resources to procure commodities.
- Access skilled personnel to procure these commodities.
- Deliver the commodities reliably to all customers at every service delivery point.

Government and nongovernmental (NGO) HIV/AIDS control program staff may have only recently begun to acquire the skills needed to accurately quantify their HIV commodity needs. To date, many HIV/AIDS interventions are small-scale pilot interventions that work well because a large number of human and financial resources are focused on a small audience. Quantification of the commodity needs and management of the supply chain for small programs is relatively uncomplicated. Replicating these activities on a national scale with proportionally fewer resources, however, poses a major challenge for country programs and donors.

B. Why HIV Tests?

Many countries are already facing this challenge as they begin to estimate national requirements for HIV tests. Rapid HIV test devices and other HIV tests are relatively new to commodity management portfolios. In addition, HIV test technology is evolving rapidly, with new tests being developed and a wide array of test brands already available on the international market. Unlike essential drugs, many countries do not have a national list to control the import of HIV tests. The World Health Organization (WHO) recommends a short list of tests. Having fewer brands facilitates quality assurance, supply management of HIV tests, and training of providers in the use of HIV tests.

This guide presents a process for quantifying HIV test requirements in developing country settings using a variety of forecasting methodologies. It is intended to help program managers and logistics advisors select recognized methodologies and apply them based on specific country circumstances.

These circumstances may include—

- epidemiological profile/disease prevalence
- capacity of the logistics system, service provision system, and human resources
- program maturity
- political will
- financial resource constraints.

This guide does not cover the quantification of the supplies and disposable items that are required for some HIV test kits. These items are very specific to the type and brand of kit chosen. Additionally, an increasing number of newly developed HIV rapid test kits are self-contained and do not require additional supplies.

This guide does not cover the selection, procurement, storage, distribution, and end use of HIV tests.

2. Background

Prior to quantifying HIV test requirements, it is important to have a basic knowledge of HIV tests and HIV testing.

A. Types of HIV Tests

Currently, there are more than 70 brands of HIV tests, and the technology is evolving rapidly. In the next few years, many new tests will likely replace current ones. The majority of HIV tests being used in developing country settings fall into one of the three basic groups shown in table 1.

Table 1. HIV Tests

Test	Site of Use	Advantages	Limitations	Cost
Simple/rapid assay (Rapid test device or RTD)	Small labs, VCT sites, PMTCT sites, STD 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. ▪ Many newer tests can be stored at room temperature. ▪ When used in combination, results as reliable as ELISAs. ▪ Can be used on various types of specimens, including whole blood. ▪ Oral fluid tests have been developed recently, are non-invasive, and do not require sharps. ▪ Can be used to do on-site/point of care testing.	▪ Small-scale testing. ▪ Considerable variation in sensitivity. However, this often depends on type of specimen (i.e., whole blood, serum, oral fluid). ▪ Cold chain sometimes required. ▪ May cost more per individual test. ▪ Some products are less sensitive for seroconvertors. ▪ Using rapid tests at multiple sites in resource poor countries poses quality assurance challenges.	Relatively expensive.
ELISA	Large hospitals, blood banks, or reference laboratories.	▪ Highly sensitive, especially for picking up seroconvertors. ▪ Batch testing. ▪ Can be automated. ▪ Easier to conduct quality assurance testing, because tests are performed in fewer, high-volume laboratories.	▪ 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.	Relatively more expensive than rapid test device, but cost-effective with large batches. Can be expensive if only used for small batches.
Western blot	Large teaching hospitals, reference laboratories, and National Reference Laboratory.	▪ The "Gold Standard." ▪ Detects all antibodies present.	▪ Requires skilled and experienced personnel. ▪ Non-routine test (small batches only, usually < 10) used for research and clarifying indeterminate results.	Very expensive.

Rapid Test Devices (RTDs) are also ELISAs, but are listed as a separate type because of the nearly immediate results provided and because of other characteristics of the tests. Traditional ELISAs are sometimes referred to as long ELISAs because they take up to three hours to produce a test result.

B. Primary Uses of HIV Tests

- ***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 other infectious diseases allows for infected or suspect blood to be discarded or destroyed, thereby ensuring the safety of the blood supply. 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 2001). 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, the donors are not informed of the results of testing (unlinked testing).

- ***Voluntary Counseling and Testing (VCT):*** Voluntary HIV counseling and testing (VCT) is now acknowledged as 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 tuberculosis 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 based on the result, will be lost.[1]

- ***Prevention of Mother-to-Child Transmission (PMTCT)*:** 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 MTCT during pregnancy and delivery, and an additional 10–20 percent risk through breastfeeding. In some countries, HIV testing for PMTCT is voluntary. In these cases, the percentage of pregnant women who seek testing must be considered as part of the quantification formula. In other countries, testing is mandatory, 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 (Department of Health, Cape Town 2002):*** All babies born to HIV-positive mothers are HIV-exposed. All HIV-exposed babies should be HIV tested at nine months of age using rapid HIV tests. The nine-month age is chosen for the HIV testing because it can be coordinated with the nine months of age immunization visit. At nine months, or at any age, an HIV-negative test means the baby is uninfected, unless the baby is being breastfed. Breastfed babies can contract HIV infection from breast milk. All breastfed babies, even if testing HIV-negative at nine or 18 months,

should be retested three months after weaning from breast milk in those cases where breastfeeding continues for longer than 4–6 months. Babies testing HIV-positive at nine months should be retested at 18 months. The 18-month retesting is necessary because some babies who test positive at nine months are actually false positives because they are slow in clearing their maternal HIV antibodies. An HIV-positive test at 18 months or older confirms HIV infection in an HIV-exposed baby.

- ***Clinical Diagnosis:*** HIV testing is conducted when an inpatient or outpatient shows signs and symptoms of AIDS, when health workers and care providers suffer needle stick or exposure to bodily fluids of a known HIV-positive person (post-exposure prophylaxis), and when a person is a victim of sexual assault. Individuals requiring a certificate of HIV sero-status for employment, marriage, schooling, visas, etc., might also be tested in a clinical setting.

  Because of the varied circumstances under which HIV tests are given for clinical diagnosis, it can be difficult to conduct quantification. In some cases, there may be no separate clinical diagnosis program and no separate HIV test procurement activity for diagnostic testing. In these cases, there may not be defined testing protocols. If so, the protocols used are likely to vary considerably, complicating the quantification calculations. Data for quantification in these situations is likely to be difficult to obtain as well, because most health management information systems (HMIS) and periodic surveys do not capture the required information. In spite of these difficulties, the use of HIV tests for clinical diagnosis must be considered in quantifying HIV test requirements. If not, HIV tests intended for blood safety or other uses may be diverted for diagnostic testing, resulting in a shortage of tests for the intended purpose.

- ***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 results, or it 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 (DHS). It could also include large scale institutional testing of special populations such as military, police, prisoners, etc., who may not necessarily go to traditional VCT or clinical sites.

C. HIV Testing Protocols

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

The following are examples of testing protocols:

Serial Protocols

Protocol S1	Protocol S2	Protocol S3
A	A B	A B C
If positive, result is positive. If negative, result is negative.	If test A positive, run test B. If test B positive, result is positive. If test B negative, results inconclusive. If test A negative, result is negative.	If test A positive, run test B. If test B positive, result is positive. If test B negative, run test C. If test C is positive, result is positive. If test C is negative, result is negative. If test A negative, result is negative.

S = serial testing **P** = parallel testing

If protocol S3 above, or protocols P1, P3, or P4 below are 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. In addition, if Protocol P4 is being used, the person conducting the quantification must determine the average discordance between all brands of Test C and all brands of Test D. These discordance rates become the basis for determining the number of tie-breaker tests required.

Parallel Protocols

Protocol P1	Protocol P2	Protocol P3	Protocol P4
AB C	A BC	AB CD	AB CD E
Tests A and B run in parallel. If tests A and B both negative, result is negative. If tests A and B both positive, result is positive. If tests A and B discordant, run test C. If test C positive, result is positive.	If test A negative, result is negative. If test A positive, run tests B and C in parallel. If one or both of tests B and C, positive, result is positive. If tests B and C both negative, result is negative.	Tests A and B run in parallel. If tests A and B both negative, result is negative. If tests A and B both positive, result is positive. If tests A and B discordant, run tests C and D in parallel. If tests C and D both negative, result is negative. If tests C and D both positive, result is positive. If tests C and D discordant, results are inconclusive.	Tests A and B run in parallel. If tests A and B both negative, result is negative. If tests A and B both positive, result is positive. If tests A and B discordant, run tests C and D in parallel. If tests C and D both negative, result is negative. If tests C and D both positive, result is positive. If tests C and D discordant, run test E. If test E positive, result is positive. If test E negative, result is negative.

3. Quantification

Quantification is the general term for the process of estimating the quantities of specific drugs, laboratory reagents, and consumable medical supplies required to serve customers in a health program for a given period of time. Quantification is accomplished in the following eight steps or stages:

1. Define the program you are quantifying.
2. Collect the data required to complete all remaining steps.
3. Forecast demand and adjust for quality control, wastage, and service capacity.
4. Estimate quantities required.
5. Calculate financial requirements.
6. Reconcile available funding and quantities required.
7. Present findings to decision makers to determine quantities to procure.
8. Update and revise the quantification as new, more accurate data becomes available.

This quantification guide presents the process for completing each of the stages when quantifying for HIV test requirements.

A. Define the Program

Before beginning the actual HIV test requirements quantification, it is important to clearly define the program(s) you are quantifying.

From a logistics perspective, a *program* is 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, this is considered one program and requires one quantification.

Conversely, the 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., the MOH distribution system and the Mission sector distribution system, each of these pipelines is considered a different program. Quantification must be conducted for each program.

Example 1. In Country X the funds for test kits for blood safety are provided by the government, the funds for test kits for VCT and PMTCT are provided by the European Union, and the funds for test kits for sentinel surveillance are provided by the Centers for Disease Control and Prevention (CDC). However, all the kits are stored and distributed under the MOH system for HIV/AIDS-related products. In this case, you would quantify for each of these four purposes and then aggregate the quantities required to determine the total quantities of kits required by the MOH.

Example 2. In Country Y, you are asked to conduct quantification for the blood safety, VCT, and sentinel surveillance activities. As you begin your questioning you discover that the VCT and sentinel surveillance program HIV tests are procured through the MOH Public Health Unit and MOH Logistics Unit, and are distributed through the MOH regular essential drugs distribution system. The tests for blood safety are donated by an NGO, briefly stored, and then distributed separately to the government blood collection sites by a private distributor under contract to the NGO. These are two separate programs, and would require separate quantification exercises.

If there is no program to supply HIV tests for a certain purpose, e.g., clinical diagnosis, the "wastage" factor for the other purposes might have to be increased. This is because tests intended for uses such as blood safety or sentinel surveillance might be diverted to testing for clinical diagnosis, VCT, or PMTCT.

In addition to knowing the uses for HIV tests in the program, it is also necessary to gather information about how the testing services for various uses are structured. This will allow the quantifier to ask the right questions for each use and to review the correct records and reports.

Questions that will provide general background information for defining the program include the following:

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, 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?

   If yes, who supplies their HIV tests?
9. What brands and types of tests are used at what level in the program?

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?
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?

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?
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 (ANC) 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?
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?

CLINICAL DIAGNOSIS

1. Are AIDS patients routinely diagnosed through clinical diagnosis?
2. What service statistics are available on the use of HIV tests for clinical diagnosis?
3. Approximately how many and what types of sites conduct HIV testing for clinical diagnosis?
4. What consumption data is available for HIV tests for clinical diagnosis?
5. Is the testing protocol for clinical diagnosis the same throughout the country?
6. Is the testing protocol for clinical diagnosis the same in government, NGO, missionary, and private facilities?
7. From where do the NGO and mission sector sites receive their HIV tests for clinical diagnosis?
8. What brands and types of HIV tests are used at what levels in the program for clinical diagnosis?

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?

In defining the program(s), it is important to develop an HIV test flow map for each program that shows the suppliers (funding sources) of the test kits, products supplied, products supplied for which uses, and the general distribution flow of the kits from suppliers to points of use. Carefully defining the program will help avoid double-counting of some HIV test requirements and failing to count other HIV test requirements.

B. Collect Required Data

It was mentioned earlier that HIV tests have seven uses—blood safety, VCT, PMTCT, testing HIV-exposed babies, sentinel surveillance, clinical diagnosis, and others (training and special studies). Once you have determined the uses for HIV tests in the program you are quantifying and how the HIV testing services for the various uses are structured, you must gather the data needed to estimate the quantities required for each of these uses.

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—

- head of the national laboratory services
- head of blood safety/transfusion services
- head of the national AIDS control program (NACP) (usually within the Ministry of Health)
- head of the National AIDS Committee (NAC) (usually a multisectoral committee within the office of the president or head of state)
- head of national hospital services
- heads of tertiary care hospitals
- heads of local blood collection facilities (in decentralized environment)
- heads of NGOs conducting HIV tests
- donors involved in HIV/AIDS support
- procurement agents
- VCT, sentinel surveillance, blood collection/transfusion, and MTCT program field units
- private sector suppliers and testers of blood.

Program documents that are likely to provide useful information include—

- national HIV/AIDS/STI policy papers
- MOH annual reports
- MOH list of sites collecting/transfusing blood
- reports from local blood testing facilities
- AIDS commission reports
- NACP annual reports
- NACP project plans
- NACP VCT plans and reports

- NACP sentinel surveillance plans and reports
- budgetary documents or proposals
- Demographic and Health Surveys
- national essential drugs list, particularly for laboratory reagents, supplies, and materials
- HIV testing protocols
- standard treatment guidelines
- health management information system (HMIS) reports
- logistics records and reports on HIV test kit procurement, distribution, consumption, and balances
- special reports, studies from other cooperating agencies and donors, e.g., FHI, PSI, JHU/PCS, CDC, GTZ, DFID, etc.

See the reference section at the end of this paper for other HIV test kit quantification data sources.

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. To proceed with the quantification in cases where key data are not available or are of very poor quality, it may be necessary to make estimates based on information gathered from key informants.

C. Forecast Adjusted Demand

In this step of the quantification process, you forecast demand and then adjust for quality control, wastage, and service capacity. The resulting figure is the adjusted demand. Tables 2–8 present the information that must be collected for forecasting adjusted demand for each of the six uses of HIV tests.

There are four recognized methodologies that can be used to forecast demand for HIV tests. The appendix at the end of this guide explains the four methodologies and how to apply them to each of the uses for HIV tests. See the methodologies pages in the appendix for help as you work through tables 2–8.

After you have defined the program and gathered the information in tables 2–8, you can forecast adjusted demand.

Remember that you will be forecasting individual HIV tests (to test one sample). All of the calculations in this document use individual tests as the unit, until the very end of the process when the numbers of tests will be converted into the numbers of kits.

Forecast Demand

It is highly recommended that more than one of the four available methodologies be used for forecasting demand for each use of HIV tests. The results obtained should then be compared and reconciled by program managers.

Table 2. Data Required to Forecast Adjusted Demand for HIV Tests for Blood Safety

DEMAND

Logistics	Demographic/Morbidity	Service Statistics	Target
1. How many of each brand of tests were consumed the past year[3] for blood safety? 2. What is the lowest level of the system having relatively complete data? 3. For this level of the logistic system, what was the beginning inventory of each brand of test at the start of the year?[4] 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 expiries, losses, and adjustments for each brand of test for the year? 6. For this level of the logistic system, what was the ending inventory for the year? 7. What is the expected rate of change of HIV test consumption for blood safety for the year for which you are quantifying?	1. What is the population of the catchment area covered by this blood safety program? 2. What percentage of people in this population will donate blood? 3. On average, how many times does a blood donor donate per year? 4. What is the HIV prevalence rate among blood donors?[3] 5. What is the average discordance rate between the screening and confirmatory tests? 6. What is the HIV testing protocol for blood safety?	1. How many blood units were collected during the past year?[3] 2. How many blood units were transfused during the past year? 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)? 4. What is the expected rate of change in blood collection in the year for which you are quantifying? 5. What is the HIV prevalence rate among blood donors?[5] 6. What is the average discordance rate between the screening and confirmatory tests? 7. What is the HIV testing protocol for blood safety?	1. What is the targeted number of blood units to be collected in the year for which you are quantifying? 2. What is the HIV prevalence rate among blood donors?[5] 3. What is the average discordance rate between the screening and confirmatory tests? 4. What is the HIV testing protocol for blood safety?
	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 is 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 3. Data Required to Forecast Adjusted Demand for HIV Tests for Voluntary Counseling and Testing (VCT)

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

4A. On average, how many VCT 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?

- OR -

6A. If reliable service capacity data is 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.

4B. On average, how many VCT clients per day will a counselor counsel if the counselor is not conducting the tests?

5B. What percentage of counseled clients are likely to request HIV testing?

6B. For the VCT 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 VCT?

8B. On average, how many HIV tests for VCT will a technician conduct per day?

- OR -

9B. 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.

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 VCT?

Table 4. Data Required to Forecast Adjusted Demand for HIV Tests for Prevention of Mother-to-Child Transmission (PMTCT)

DEMAND			
Logistics	**Demographic/Morbidity**	**Service Statistics**	**Target**
1. How many of each brand of tests were consumed during the past year[3] for PMTCT? 2. What is the lowest level of the system having relatively complete data? 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] 4. For this level of the logistic system, what were the receipts for each brand of test for the year?[4] 5. For this level of the logistic system, what were the expiries, losses, and adjustments for each brand of test for the year? 6. For this level of the logistic system, what was the ending inventory for each brand of test for the year? 7. What is the expected rate of change of HIV test consumption for PMTCT?	1. How many women of reproductive age live in the catchment area of ANC sites offering PMTCT? 2. What is the pregnancy rate in the catchment area? 3. What percentage of pregnant women in the catchment areas will make at least one ANC visit? 4. What percentage of these ANC clients is likely to request counseling for HIV? 5. What percentage of ANC clients counseled is likely to request an HIV test? 6. What is the HIV prevalence rate among PMTCT clients? 7. What is the average discordance rate between the screening and confirmatory tests? 8. What is the testing protocol for PMTCT?	1. How many pregnant women were tested for HIV in sites offering PMTCT in the past year?[3] 2. What is the HIV prevalence rate among pregnant women tested at PMTCT sites in the past year? 3. What is the average discordance rate between the screening and confirmatory tests? 4. What is the expected rate of change for PMTCT testing? 5. What is the testing protocol for PMTCT?	1. What is the targeted number of clients to be tested for PMTCT in the year you are quantifying? 2. What is the HIV prevalence rate among PMTCT clients? 3. What is the average discordance rate between the screening and confirmatory tests? 4. What is the testing protocol for PMTCT?
	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?

- OR -

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?

- OR -

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?

Table 5. Data Required to Forecast Adjusted Demand for HIV Tests for Testing HIV-Exposed Babies

DEMAND			
Logistics	**Demographic/Morbidity**	**Service Statistics**	**Target**
1. How many of each brand of tests were consumed during the past year[3] for testing HIV-exposed babies? 2. What is the lowest level of the system having relatively complete data? 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] 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 expiries, losses, and adjustments for each brand of test for the year? 6. For this level of the logistic system, what was the ending inventory for each brand of test for the year? 7. What is the expected rate of change of HIV test consumption for testing HIV-exposed babies?	1. What percentage of babies of HIV-positive PMTCT clients will be brought for HIV testing at age 9 months? 2. What is the percentage of HIV-exposed babies who test HIV-negative at age 9 months? 3. What percentage of HIV-negative babies at age 9 months will still be breastfeeding? 4. What percentage of HIV-negative babies still breastfeeding at 9 months will be brought for retesting 3 months after being weaned from breast milk? 5. What percentage of HIV-exposed babies test HIV-positive at age 9 months? 6. What percentage of HIV-positive babies at age 9 months will be brought for retesting at age 18 months? 7. What percentage of HIV-negative babies at age 18 months will still be breastfeeding? 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? 9. What is the average discordance rate between the screening and confirmatory tests? 10. What is the testing protocol for testing HIV-exposed babies?	1. How many HIV-exposed babies were tested in the ANC sites offering PMTCT during the previous year?[3] 2. What was the HIV prevalence rate among HIV-exposed babies tested at ANC clinics? 3. What is the average discordance rate between the screening and confirmatory tests? 4. What is the expected rate of change for testing HIV-exposed babies? 5. What is the testing protocol for testing HIV-exposed babies?	1. What is the targeted number of HIV-exposed babies to be tested in the year you are quantifying? 2. What is the HIV prevalence rate among HIV-exposed babies? 3. What is the average discordance rate between the screening and confirmatory tests? 4. What is the testing protocol for testing HIV-exposed babies?
	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 is 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 is 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 6. Data Required to Forecast Adjusted Demand for HIV Tests for Sentinel Surveillance

DEMAND			
Logistics	**Demographic/Morbidity**	**Service Statistics**	**Target**
N/A	N/A	N/A	1. How many people will be tested for HIV in the sentinel surveillance program in the year you are quantifying? 2. How many or what percentage of the screened specimens will be tested for quality control? 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? 4. What is the testing protocol for sentinel surveillance?
	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 7. Data Required to Forecast Adjusted Demand for HIV Tests for Clinical Diagnosis

DEMAND

Logistics	Demographic/Morbidity	Service Statistics	Target
1. How many of each brand of tests were consumed in the past year[3] for clinical diagnosis? 2. What is the lowest level of the system having relatively complete data? 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] 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 expiries, losses, and adjustments for each brand of test for the year? 6. For this level of the logistic system, what was the ending inventory for each brand of test for the year? 7. What is the expected rate of change of HIV test consumption for clinical diagnosis?	1. What is the population of the catchment areas of health facilities receiving HIV tests under this program? 2. What percentage of the population in the catchment area will access medical facilities this year? 3. What percentage of individuals accessing medical facilities are tested for HIV? 4. In the catchment areas, what is the AIDS prevalence of the population accessing medical facilities? 5. What is the average discordance rate between the screening and confirmatory tests? 6. What is the testing protocol for clinical diagnosis?	1. How many HIV tests were conducted in clinical settings during the past year[3] for diagnostic testing? 2. What is the expected rate of change in HIV testing for clinical diagnosis in the year you are quantifying? 3. How many of the HIV tests conducted in the past year for clinical diagnosis testing were HIV-positive? 4. What is the average discordance rate between the screening and confirmatory tests? 5. What is the testing protocol for clinical diagnosis?	1. What is the anticipated number of clients to be tested for HIV for reasons of clinical diagnosis in the year you are quantifying? 2. What is the HIV prevalence rate of clients tested for HIV for purposes of clincal diagnosis? 3. What is the average discordance rate between the screening and confirmatory tests? 4. What is the testing protocol for clinical diagnosis?

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 clinical diagnosis, 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 clinical diagnosis?
3. On average, how many HIV tests for clinical diagnosis will a technician conduct per day?

- OR -

4. If reliable service capacity data is not available, discuss with key informants the testing capacity for clinical diagnosis. Using this information, determine the maximum number of tests that can be conducted for clinical diagnosis 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 8. Data Required to Forecast Adjusted Demand for HIV Tests for Other Uses (Including Training and Research)

DEMAND

Logistics	Demographic/Morbidity	Service Statistics	Target
1. How many of each brand of tests were consumed during the past year[3] for the other use(s) you are quantifying? 2. What is the lowest level of the system having relatively complete data? 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] 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? 6. For this level of the logistic system, what was the ending inventory for each brand of test for the year? 7. What is the expected rate of change of HIV test consumption for other uses?	N/A	1. How many clients were tested for HIV in the past year[3] for the other use(s) you are quantifying? 2. What is the percentage expected rate of change in testing for the other use(s) you are quantifying? 3. What is the HIV prevalence rate for clients tested for the other use(s) you are quantifying? 4. What is the average discordance rate between the screening and confirmatory tests? 5. What is the testing protocol for the other use(s) you are quantifying?	1. How many clients are targeted to be tested for HIV for the other use(s) you are quantifying? 2. What is the HIV prevalence rate for clients tested for the other use(s) you are quantifying? 3. What is the average discordance rate between the screening and confirmatory tests? 4. What is the testing protocol for the other use(s) you are quantifying?

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 is not available, discuss with key informants the testing capacity for the other use(s) you are quantifying. Using this information, determine the maximum number of tests that can be conducted for the use(s) 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?

ADJUST DEMAND FOR QUALITY CONTROL AND WASTAGE

Quality control

Some HIV tests require that additional tests be conducted to ensure the quality of the tests and 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. Some have an internal control feature and do not require additional tests.

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 expire, become damaged, lost, or found defective.

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

(Demand) × [1 + (quality control factor + wastage factor)]
= demand adjusted for quality control and wastage.

Use a 10 percent wastage factor as the default value if actual wastage factors are not known or cannot be accurately estimated.

MEASURE HIV TESTING CAPACITY AND COMPARE TO FORECASTED DEMAND

After adjusting forecasted demand for quality control and wastage, you must measure the program's HIV testing capacity for each of the uses of HIV tests.

HIV counseling and testing capacity is affected by skill levels of staff, staff availability, availability of HIV test kits and related supplies, and availability of functioning equipment for tests requiring use of equipment.

Using the information from the answers to the service capacity questions in tables 2–8, and determine the HIV counseling and testing capacity for each 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 sentinel surveillance if these programs do linked testing.

To calculate capacity for each use:

(Total number of technicians conducting HIV testing) × (number of days per year on average that a technician will conduct HIV testing for the specified use) × (average number of tests a technician will conduct per day for the specified use)
= HIV testing capacity for that use.

If reliable service capacity data is not available, gather testing statistics for a recent past period and discuss these with key informants 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 ELISA qualified technicians.

Compare the HIV testing capacity to the HIV tests forecasted demand figures. If the HIV testing capacity is equal to or larger than the forecasted demand figure, testing capacity does not pose a constraint.

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

The quantity resulting after the forecasted demand is adjusted for quality control, wastage, and service capacity is referred to as the adjusted demand.

D. Estimate Quantities Required

After calculating adjusted demand, it is necessary to estimate the quantities of HIV tests actually required to both meet the adjusted demand *and* to fill the pipeline to ensure a continuous supply to clients. It is also in this phase of quantification that one calculates the cold (2–8°C) storage space and room temperature (8–30°C) storage space required for the HIV tests. These space requirement figures are then compared to the actual storage space available at the level at which the tests will enter the program.

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, and for testing if the kits are to be assessed for quality 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 useable 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 are the calculations for estimating quantities required:

(a) **(Adjusted demand quantity for each brand of HIV test for one year) × (12 months) = average monthly adjusted demand (AMAD) for each brand.**

(b) **(Lead time for each brand of HIV test in months) × (AMAD for each brand) = lead time stock for each brand of test.**

(c) **(Desired buffer stock for each brand of HIV test in months) × (AMAD for each brand of HIV test) = buffer stock for each brand of test.**

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 as it is assumed to be covered by the lead time and buffer stock allowances.

(a) **For each brand of test: (adjusted demand) + (lead time stock) + (buffer stock) - (usable stock on hand at all levels of the program) - (usable stock on order) = quantity required.**

(b) **To calculate the volume at entry level for each brand of test: (adjusted demand + lead time stock + buffer stock for each brand) × (number of each brand of tests in a kit) × (volume of one HIV test kit of each brand required) = total volume of each brand of HIV test.**

(c) **(Volume of brand1 test requiring cold storage + volume of brand2 test requiring cold storage + volume of brandN test requiring cold storage) × (estimated number of shipments for the year of tests requiring cold storage) = cold storage requirement for HIV tests at the entry level.**

(d) **(Volume of brand1 test requiring room temperature storage + volume of brand2 test requiring room temperature storage + volume of brandN test requiring room temperature storage) × (estimated number of shipments for the year of tests requiring room temperature storage) = 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 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 plus buffer stock volume, 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 upon arrival.

E. Calculate Financial Requirements

To calculate financial requirements for the quantities of tests required, the quantifier must obtain answers to the following questions:

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

To estimate the cost of the total numbers of HIV tests required:

(a) 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.

(b) Discuss with key informants and review past purchase records to determine the likely cost per kit for each brand of kit, and/or

Consult standard price references, e.g., *Sources and prices of selected drugs and diagnostics for people living with HIV/AIDS:* June 2003. UNICEF, UNAIDS, WHO, and *Medecins Sans Frontieres,* to determine estimated costs per kit.

(c) Multiply the cost per kit for each brand times the number of kits of each brand to determine the total cost for each brand of test kit.

(d) Add these totals to determine the grand total 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.)

(e) Determine the cost of insurance and freight for this volume/value of kits, if applicable.

(f) Determine the costs of customs duties and customs clearance for this volume/value of HIV tests and add this amount to the financial requirements.

(g) Determine any direct storage and distributions costs on this volume/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. This will help ensure that program managers are aware of these costs, and can make provisions for them prior to the arrival of the HIV tests into the program. If these costs are not budgeted for in advance, there is a danger of the tests being delayed in customs clearance and in the distribution pipeline, resulting in loss of product through expiration.

If the main purpose of the quantification is to estimate financial requirements to request funding, the quantification ends at this point.

F. Reconcile Available Funding and Quantities Required

To reconcile available funding and quantities required, you must ask the following questions:

1. What are the sources of funding for HIV tests?
2. How much funding is available from each source of funding for this quantification period?
3. Is funding from some sources available only for specific uses of HIV tests?

With the answers to these statements:

(a) Compare the financial requirements for HIV tests to the funding available for HIV tests from government sources and donors.

(b) If available funding is greater than the financial requirements for the tests, procure only the quantities required. Do *not* order additional tests just to use all the available funds as this would probably result in financial losses through expiration of the tests.

(c) If available funding is less than the financial requirements for the quantities of tests required, advise program managers to seek additional funding.

(d) If additional funding cannot be secured, advise program managers that they must 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 prioritizing the purposes, e.g., blood safety, VCT, PMTCT, sentinel surveillance, clinical diagnosis, and other uses for the kits and reduction of quantities to be procured to fit available funds. It could also involve revisiting previous decisions regarding protocol. But, regardless of whether you change the protocol or keep the same one, be sure to procure kits in the proper proportion to ensure that the protocol can be completed.

G. Present Findings to Decision Makers

After the preliminary quantification is completed, it is recommended that the persons doing the quantification convene a validation workshop with representatives of all stakeholders in HIV testing. In this workshop the methodologies, assumptions, and outcomes of the quantification should be presented and reviewed. Participants should comment on the findings, correct any assumptions that are not valid, and, to the extent possible, reach a consensus on the quantities required and the financial requirements.

You must then present the validated quantification findings to top decision makers in an easily digestible form. In addition to a written report with an executive summary covering any major issues, it is desirable to make a presentation to top management where they have an opportunity to ask for clarifications. If available funding is less than the financial requirements for the quantity required, this meeting should serve as a forum for discussing the possibility of securing additional funding. If it is clear that additional funding will not be forthcoming, this meeting should serve as a forum for determining priorities for uses of HIV tests. Ideally, this meeting should result in decisions on quantities to procure for each brand/type of HIV test. To the greatest extent possible, HIV/AIDS program staff should present or participate in the presentation to top decision makers to show their involvement and buy-in to the findings.

Program managers should be advised of the quantities to be procured, and should ensure that adequate storage and distribution arrangements are in place at all lower levels of the system.

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

1. All other technical factors being equal, preference in selection should be given to HIV tests that do not require cold storage, have the longest shelf lives, and are as self-contained with peripheral supplies as possible.
2. 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 slowing down the delivery of test kits to the program depending on the actual consumption of the test kits.
3. The shipment schedule for the HIV tests must reflect the lead time and shelf life for each product as well as 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 kits with a longer shelf life that can be stored at room temperature. The in-country pipeline for these 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.
4. 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 paper work.

4. Automating Quantification

Because of the multiple uses of HIV tests, the varying methodologies that can be used to forecast demand, the potentially large number of brands of tests that might be available, and the benefit of generating multiple quantification scenarios for comparison, e.g., low, medium, and high growth in testing rates, the actual calculations can become relatively complex. There are advantages to having portions of the process automated.

John Snow, Inc., has developed ProQ, a software program for the quantification of HIV test requirements.

For information about ProQ contact:

ProQ Program Associate
JSI/DELIVER
1616 N. Fort Myer Dr.
11th Floor
Arlington, VA 22209-3100
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5. Appendix: Methodologies

Logistics: 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 is 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 (NGO). 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.[2] 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., SDP, 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?

Calculate estimated consumption for each brand:

(Beginning inventory + receipts) ± (losses/adjustments)
− ending inventory
= estimated consumption for the year.

Compare the consumption of tests in question one 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 based on 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.

The estimated consumption of each brand of test for the past year
× (1 + the change factor in decimal form)
= estimated demand for the year 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?

(Estimated consumption for the year) ÷ (number of days the facilities had tests in stock) × (number of days the facilities were stocked out of tests) = estimated number of tests that would have been consumed during periods of the stockout.

Add this number to the (estimated consumption for the year).[2]

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

BLOOD SAFETY

Question 1–Through 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–From published guidelines for blood safety, discussions with key informants, and field observations, determine 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:

(Population of the service area) × (% of population donating blood) × (times per year that a donor donates blood)
= estimated units of blood to be collected
= demand for HIV screening tests.

(Units of blood to be collected) × (blood donor HIV prevalence rate)
= demand for HIV confirmatory tests.

(Demand for HIV confirmatory tests) × (discordance rate between HIV screening and confirmatory tests)
= demand for HIV tie breaking tests.

If parallel testing protocol P1, 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:

(Population of service area) × (% of population likely to come for VCT counseling) × (% of counseled clients likely to accept testing)
= demand for HIV screening tests.

(Demand for HIV screening tests) × (HIV prevalence rate among VCT clients)
= demand for HIV confirmatory tests.

(Demand for HIV confirmatory tests) × (discordance rate between screening and confirmatory tests)
= 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:

(Women of reproductive age in PMTCT site service areas) × (pregnancy rate in the service areas) × (% of pregnant women making one ANC visit to program facilities) × (% of ANC clients likely to request HIV counseling) × (% of counseled women likely to accept HIV testing)
= demand for HIV screening tests for PMTCT.

(Demand for HIV screening tests for PMTCT) × (HIV prevalence rate among PMTCT clients)
= demand for HIV confirmatory tests.

(Demand for HIV confirmatory tests) × (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:

(Number of babies born to HIV+ PMTCT clients) × (% of babies of HIV+ PMTCT clients who will be brought for HIV testing at age 9 months)
= A, the demand for HIV screening tests for HIV-exposed babies tested at age 9 months.

A × (HIV prevalence rate of HIV-exposed babies)
= B, demand for confirmatory tests for HIV-exposed babies tested at age 9 months.

B × (discordance rate between screening and confirmatory tests)
= C, demand for tiebreaker tests for HIV-exposed babies tested at age 9 months.

B × (% of babies testing positive at age 9 months who will be brought for retesting at age 18 months)
= D, demand for HIV screening tests for HIV-exposed babies tested at age 18 months.

D × (HIV prevalence rate of HIV-exposed babies testing at age 18 months)
= E, demand for HIV confirmatory tests for HIV-exposed babies testing at age 18 months.

E × (discordance rate between the screening and confirmatory tests)
= F, demand for tiebreaker tests for HIV-exposed babies tested at age 18 months.

A + D = total demand for screening tests for HIV-exposed babies for the year for which you are quantifying.

B + E = total demand for confirmatory tests for HIV-exposed babies for the year you are quantifying.

C + F = total demand for tiebreaker tests for HIV-exposed babies for the year you are quantifying.

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.

CLINICAL DIAGNOSIS

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

(Population of clinic service areas) × (% if population is likely to access program clinics) × (% of population accessing program clinics who will show signs and symptoms of AIDS)
= demand for HIV screening tests for clinical diagnosis.

(Demand for HIV screening tests for clinical diagnosis) × (HIV prevalence rate among clinic patients)
= demand for HIV confirmatory tests for clinical diagnosis.

(Demand for HIV confirmatory tests for clinical diagnosis) × (discordance rate between screening and confirmatory tests)
= demand for HIV tie breaking tests for clinical diagnosis.

Service Statistics: 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, 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 – the discard rate) = number of units collected.

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

(Units of blood collected in the past year) × (1 +expected rate of change in blood collection)
= units of blood to be collected in the forecast year
= demand for HIV screening tests.

(Demand for screening HIV tests) × (HIV prevalence rate among blood donors)
= demand for HIV confirmatory tests for blood safety.

(Demand for confirmatory tests for blood safety) × (discordance rate between screening and confirmatory tests)
= 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:

(VCT clients tested in the past year) × (1 + expected rate of change in VCT testing)
= demand for HIV screening tests for VCT in the year you are quantifying.

(Demand for screening tests for VCT) × (HIV prevalence rate among VCT clients)
= demand for HIV confirmatory tests for VCT.

(Demand for HIV confirmatory tests for VCT) × (Discordance rate between screening and confirmatory tests)
= demand for HIV tie breaking test for VCT.

PREVENTION OF MOTHER-TO-CHILD TRANSMISSION

The demand for HIV tests for PMTCT under testing protocol S3 is calculated as follows:

(Number of pregnant women who were tested for HIV in the past year in the PMTCT program)
× (1 + expected rate of change in PMTCT testing)
= demand for HIV screening tests for PMTCT in the year for which you are quantifying.

(Demand for screening tests for PMTCT) × (HIV prevalence rate among PMTCT clients)
= demand for HIV confirmatory tests for PMTCT.

(Demand for HIV confirmatory tests for PMTCT) × (Discordance rate between HIV screening and HIV confirmatory tests)
= demand for HIV tiebreaker tests for PMTCT.

TESTING OF HIV-EXPOSED BABIES

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: 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—

The number of clients or blood samples targeted
= the demand for HIV screening tests.

(Demand for HIV screening tests) × (HIV prevalence rate for the target group)
= demand for HIV confirmatory tests.

(Demand for HIV confirmatory tests) × (discordance rate between screening and confirmatory tests)
= demand for HIV tie breaking tests.

For sentinel surveillance, the WHO protocol recommends only one test, so no confirmatory test is used. Some number or percentage of screening samples are 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.

Guide for Forecasting and Quantification of ARV Drugs

December 2005

Contents

Abbreviations and Acronyms

3TC	lamivudine
ABC	abacavir
AIDS	acquired immuno-deficiency syndrome
AMQR	average monthly quantity required
ART	antiretroviral therapy
ARV	antiretroviral drug
AZT	zidovudine
ddI	didanosine
d4T	stavudine
EFV	efavirenz
FDA	Food and Drug Administration [U.S.]
FTC	emtricitabine
HAART	highly active antiretroviral therapy
HIV	human immunodeficiency virus
IDV	indinavir
LPV/r	lopinavir + ritonavir
NFV	nelfinavir
NVP	nevirapine
OI	opportunistic infection
PEP	post-exposure prophylaxis
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PMTCT	prevention of mother-to-child transmission
SQV	saquinavir
TB	tuberculosis
TDF	tenofovir
VEN	vital, essential, nonessential
WHO	World Health Organization
ZDV	zidovudine

Foreword

A major challenge to initiation and expansion of antiretroviral therapy (ART) services in the countries 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 needed at service delivery sites to support HIV prevention, care, and treatment programs. Successful ART depends not only on the continuous availability of high-quality antiretroviral (ARV) drugs but also on the supply of a wide range of HIV/AIDS-related commodities, including 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. Therefore, an urgent need exists to strengthen and coordinate the supply chain operations of forecasting, financing, procurement, and delivery of HIV/AIDS-related commodities at the global level and to develop supply chain management capacity at the country level.

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 this paper addresses some general considerations for managing the supply chain for ARV drugs, the primary focus and purpose of the guide is to describe the process and the methodologies used for forecasting and quantifying ARV drug needs. Other 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 on forecasting and quantification of ARV drugs draws from the collected 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 of the countries hardest hit by the epidemic. This experience indicates that the two most critical supply chain interventions for ART programs now are to:

- Establish robust data collection and reporting systems to improve the availability and quality of data on ART services and commodities
- Develop expertise in forecasting and quantification of ARV drug requirements for governments and programs to permit informed decision-making regarding financing and procurement of commodities

The DELIVER experience and lessons learned in forecasting and quantification of ARV drugs in eight countries have been incorporated into the step-by-step approach to quantification presented in this guide. Examples

from Excel spreadsheets that were used in developing a quantification for a national ART program are attached in the annexes to this paper. The authors hope that this document will prove useful as a guide for conducting the overall quantification exercise itself, as well as provide methodologies for forecasting and estimating drug requirements for a specific country or program. It is important to keep in mind 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 management information systems improve to enable more evidence-based rather than assumption-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 ART and management of ARV drug supply chains.

Challenges and Lessons Learned in Quantification of ARV Drugs

The following challenges have been summarized from the DELIVER experience in ARV drug forecasting and quantification that led to the approach to quantification presented in this guide:

- Data on ART services and ARV drug supply is scarce and when available, is often of insufficient quantity and quality to be used for forecasting and quantification.
- Standard treatment guidelines are inconsistent, are in need of revision, or have not been widely disseminated to providers.
- Program targets do not take into account service delivery and supply chain capacity.
- Program expansion does not occur as rapidly as expected.
- Multiple sources of funding, procurement mechanisms, and distribution channels are used for ARV drugs.
- Forecasting and quantification capacity is limited at country and program levels.
- Communication and coordination are lacking between policymakers, service providers, funding sources, and procurement agents on issues related to the selection, quantification, and procurement of ARV drug needs
- Quantification and procurement occur when funding becomes available rather than as a program planning activity that identifies commodity needs and mobilizes resources for procurement, leading to stockouts and more expensive emergency procurements.
- More recently, worldwide supplier shortages of certain ARV drugs may need to be addressed in the quantification to identify alternate sources of supply for the required quantities of product.

The following lessons have been learned from DELIVER's work in forecasting and quantification of ARV drugs:

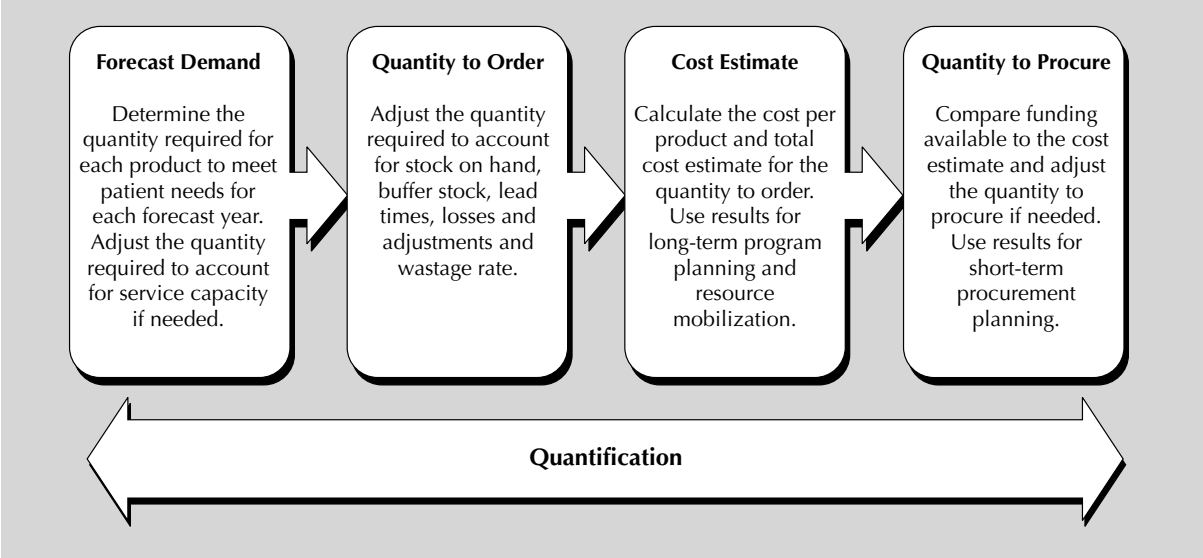
- The quantification exercise itself is time and resource intensive. Adequate time and resources to conduct the quantification exercise need to be planned for.
- Quantifications are heavily assumption based but will become more evidence based over time as availability and quality of data improve.
- Quantification requires a consultative process with multiple stakeholders to inform the assumptions about the selection, quantification, and procurement of ARV drugs.

- The quantification should be based on realistic program plans and available financing.
- The results of the quantification should be used for medium- and long-term program planning and resource mobilization for ART.
- Quantification results can also be used to determine quantities to order and shipment schedules for short-term procurement planning with available funding.
- The quantification should be reviewed and updated at least every six months, and procurement plans should be adjusted accordingly.

Introduction to Forecasting and Quantification

Figure 1 represents the steps in the quantification process for estimating the quantities and cost of products needed to meet future demand for services and maintain a full supply, taking into account service delivery capacity, supply chain capacity, and resources available for procurement.

Figure 1.
Steps in Quantification



Definition of Terms

To understand the quantification process, one must first understand the meaning of several terms.

Forecast Demand (Quantity Required)

Forecasting demand requires ascertaining the estimated quantity required of each product needed (drugs to be dispensed, commodities to be used) to meet demand for a future period of time. For public health commodities, the forecast quantity required must be adjusted to reflect the program's current service capacity (volume of services that can be provided); human

resource capacity (staff availability and training); and other environmental, political, and programmatic factors. The quantity required should include quantities to cover estimated losses and adjustments for defective, damaged, or expired product and, in the case of laboratory reagents, quantities used for laboratory controls, quality testing, and training.

Depending on the purpose of the quantification, the required quantity for products with multiple uses may need to be forecast separately for each use.

Medium-term forecasts of commodity requirements for two to five years should be prepared to guide program planning as well as resource mobilization and allocation efforts to support expected program growth.

Requirements Estimation (Quantity to Order)

Requirements estimation means determining the quantities of commodities to be ordered to meet demand *and* fill the pipeline to ensure continuous supply. The quantity to order 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. In arriving at the quantity to order for the next one-year period, one must make adjustments to account for lead time, buffer stock, stock on hand, and quantity on order. The estimated quantity to order and shipping schedules may need to be further adjusted to reflect current storage and distribution capacity of the logistics system.

Estimation of Financial Requirements (Cost Estimate)

Estimating financial requirements involves calculating the cost of the quantity to order of each product and arriving at the total cost estimate for all products needed to ensure full supply. Shipping, storage, and distribution costs may also be included in the total cost estimate, if required.

Comparison of Cost Estimate against Funding Available (Quantity to Procure)

In situations of limited funding, the quantities of commodities to be procured may need to be reduced according to the amount of funding available for procurement. Commodity needs may have to be reconciled against funding available to arrive at a specific allocation of resources for procurement. For most public health programs, this step involves prioritizing the items to be purchased and reducing the quantity to procure to fit available funds. In such cases, epidemiological profiles; ABC analysis, VEN (vital, essential, nonessential) analysis, or both; or other criteria may be used to arrive at the quantity of product to be procured. In HIV/AIDS programs, this step may result in a reduction in the number of people who can be tested for HIV or in the number of patients who can initiate ART within the period of the forecast. Comparing the total cost estimate for procuring the quantity to order that is needed to ensure full supply with the quantity that can be procured with available funding serves as a useful tool for identifying funding gaps and advocating for resource mobilization.

Quantification

Quantification is the general term for the process or methodology for estimating the quantities of product (for example, drugs, laboratory reagents, and consumable medical supplies) needed to support service provision, fill the supply pipeline, and maintain full supply for a specified period. Quantification includes the steps of forecasting demand; estimating requirements; calculating the cost estimate for purchasing the quantities of commodities needed; and, finally, adjusting the quantities to procure according to the amount of funding available, if needed.

The results of a quantification may be used (a) to estimate the quantity and cost of commodities needed over the period of the forecast to assist in long-term program planning and resource mobilization efforts and (b) to calculate specific order quantities and plan shipment schedules for immediate-term procurement planning.

Forecasting Methodologies

In general, the methodology 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 (for example, age, sex, geographic location, and urban or rural environment)
- 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 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 these 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 can 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 drug requirements because they do not take into account the actual volume of services being provided or that can be provided, the quantities of drugs in stock and being dispensed, or the

amount of funding available for commodity procurement. Wherever possible, service statistics data on the actual number of patients being treated and logistics data on the actual quantities of drugs dispensed to patients or commodities used should be incorporated into the forecast.

The *consumption-based methodology* uses logistics data on consumption of commodities in the past as a basis for projecting future needs. Estimates of increases 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 this 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 and expanding programs. Assumptions will need to be made about the rate of program growth, prescribing and dispensing practices, and patient needs to complete the quantification.

The *adjusted consumption methodology* is an adaptation of the consumption-based methodology that uses the consumption data of 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 commodities used at one or more service delivery sites.

In the *morbidity-based methodology*, the estimation of 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 forecast for may be based on demographic data, morbidity data, service statistics data, or program targets, as previously discussed. Using this methodology for estimating commodity requirements requires that data on the actual number of patients treated, or services provided, and on 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 are followed and the prescribed drugs or commodities needed are available.

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.

Issues Specific to Forecasting and Quantification of ARV Drugs

Forecasting ARV drug requirements is particularly challenging because ARV drug regimens must be adjusted over time to capture the changing needs of patients caused by side effects and toxicities to individual drugs, changing body weight, pregnancy, HIV/TB co-infection, treatment failure, and drug resistance, as well as to meet the special needs of pediatric patients. Forecasts may also need to account for patients on nonstandard ARV drug regimens, such as patients who are not naive to treatment who may have entered the program already on ART and 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, when and where they need them; and of the financial resources available for procurement have been taken into consideration. Overly optimistic or unrealistic program targets have resulted in overestimation of drug needs leading to excess procurement and wastage of limited resources on products that could not be distributed or used before they expired.

Forecasting ARV drug requirements requires the following data to be available or arrived at through informed assumptions:

- The number of existing patients
- The estimated number of new patients to be diagnosed and treated within the period of the forecast
- The percentage of patients who will be on each of the ARV drug regimens listed in the national standard treatment guidelines, including specific information on the percentage of patients currently on first-line and second-line regimens, the rate of single-drug substitutions because of toxicities and side effects, and the rate at which patients will need to make a complete regimen switch from a first-line to a second-line regimen because of treatment failure or drug resistance

The more complete and reliable the data is, and the more closely standard treatment guidelines are adhered to, the more accurate the forecast will be. To enhance accuracy of the quantification using the morbidity-based methodology, standard treatment guidelines should be clearly documented and disseminated, and all service providers should be adequately trained in ART.

Given 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 wide 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 used to inform the assumptions for the quantification is important. The quantification should be reviewed and updated at least every six months as well as when any of the major assumptions change.

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 capacity, patient access to treatment and uptake, and patient adherence and follow up
- Length of time before patients will experience side effects, toxicity, treatment failure, and 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

Background

Successful ART depends on lifelong patient adherence to prescribed ARV drug regimens and maintenance of a full supply of ARV drugs at ART sites. The threat of viral resistance and changes in patients' response 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 are available when and where patients need them at an acceptable cost. To achieve this goal, 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. This knowledge must be incorporated into the forecasting and quantification of needs to ensure procurement of the right quantities of the right drugs.

Specific Characteristics of ARV Drugs

Lifelong ART, also known 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 to facilitate 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 the 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 three completely different ARV drugs for second-line regimens must be available for patients who develop viral resistance to first-line drugs. Specific formulations for pediatric treatment regimens include oral suspensions (syrups) and dosages adjusted for weight and body surface area measurements. Updating forecasts will be important 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. Readers may refer to the DELIVER *ARV Drug Logistics Fact Sheets* for information on suppliers, packaging, storage, shelf life, and pricing of these and other ARV drugs, and to the World Health Organization (WHO) publication *Scaling Up Antiretroviral Therapy in Resource-Limited Settings: Treatment Guidelines for a Public Health Approach* for further information on adult and pediatric dosing regimens and prescribing guidelines. (See the list of references at the end of the DELIVER *Guidelines for Managing the HIV/AIDS Supply Chain*). These lists are not intended to be exhaustive and readers should refer to in-country standard treatment guidelines, WHO guidelines, and 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 or generic manufacturers. Originator ARV drugs are generally more expensive than generic drugs, with a few exceptions. Some drug combinations are available either only from generic manufacturers (for example, most triple fixed-dose combinations, with a couple of exceptions, are generic) or only from originator manufacturers (for example, LPV/r is produced as Kaletra). Voluntary licensing and price reductions by both originator 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, their procurement with U.S. government funds for Africa and developing countries through the U.S. President's Emergency Plan for HIV/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.

Table 1. Single-Drug Formulations (Illustrative List Only)

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

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, which can reduce frequency and severity of side effects.

Table 2. Fixed-Dose Combination Drugs (Illustrative List Only)

Stavudine (30 mg) + lamivudine 150 mg tablet ($d4T_{30}$/3TC)
Stavudine (40 mg) + lamivudine 150 mg tablet ($d4T_{40}$/3TC)
Stavudine (30 mg) + lamivudine 150 mg + nevirapine 200 mg tablet ($d4T_{30}$/3TC/NVP)
Stavudine (40 mg) + lamivudine 150 mg + nevirapine 200mg tablet ($d4T_{40}$/3TC/NVP)
Zidovudine 300 mg + lamivudine 150 mg tablet (AZT/3TC or ZDV/3TC)
Zidovudine 300 mg + lamivudine 150 mg + abacavir 300 mg tablet (ZDV/3TC/ABC)
Tenofovir 300 mg + emtricitabine 200 mg tablet (TDF/FTC)

Types of ART and Common ARV Drug Regimens

Antiretroviral therapy regimens for the prevention of mother-to-child transmission of HIV, (PMTCT), 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- and second-line treatment regimens for adults and children (see table 3). Forecasts of ARV drug requirements for each of these interventions should be included in the quantification.

Logistics Management of ARV Drugs

The most challenging aspect of ART is that it is lifelong treatment that must be monitored and customized over the life of the patient. Logistics management of ARV drugs requires enhanced flexibility in financing, forecasting, procurement, and delivery to be able to respond to changes in patient demand over time. The ability of the logistics system to provide single-drug substitutes, more user-friendly fixed-dose combinations, second-line drugs, and pediatric formulations, as needed, is critical. A maximum–minimum inventory control system should be established to ensure product availability at all ART sites and to maintain full supply for the lifetime of all patients who initiate ART.

The logistics management information system for ARV drugs should capture data on drug consumption and the number of patients on each ARV drug regimen and should have access to clinical data on patient responses to treatment over time to be able to forecast for expected rates of change in ARV drug regimens. Any revisions in prescribing and dispensing guidelines should be incorporated into national forecasts and procurement plans.

The high cost of ARV drugs and their life-saving potential can make them highly subject to pilferage and leakage. Therefore, secure storage facilities and reliable transportation systems are needed to ensure the quality and security of ARV drugs throughout the supply pipeline. The relatively short shelf life of ARV drugs (18 to 36 months) requires strict monitoring of inventory levels to ensure product quality and to avoid expiration of the product.

Table 3. Examples of Common ARV Drug Regimens (Illustrative List Only)

Adult First-line Regimens	Adult Second-line Regimens	Adult HIV/TB Co-infection	Pediatric First-line Regimens	Pediatric Second-line Regimens	Pediatric HIV/TB Co-infection	PMTCT	Post-exposure Prophylaxis
d4T + 3TC + NVP	TDF + ddI + LPV/r	d4T + 3TC + EFV	d4T + 3TC + NVP	ABC + ddI + NFV	d4T + 3TC + ABC	ZDV + 3TC (mother)	High-risk exposure ZDV + 3TC + IDV
d4T + 3TC + EFV	TDF + ddI + SQV/r	d4T + 3TC + ABC	d4T + 3TC + EFV	ABC + ddI + LPV/r	ZDV + 3TC + ABC	ZDV + 3TC (infant)	ZDV + 3TC + NFV
d4T + 3TC + NFV	TDF + ddI + IDV/r	d4T + 3TC + SQV/r	d4T + 3TC + NFV	ABC + ddI + SQV/r			
d4T + 3TC + LPV/r						NVP 200 mg tablet (mother)	Low-risk exposure ZDV + 3TC
						NVP 10 mg/ml syrup (infant)	
ZDV + 3TC + NVP	ABC + ddI + LPV/r	ZDV + 3TC + EFV	ZDV + 3TC + NVP				
ZDV + 3TC + EFV	ABC + ddI + SQV/r	ZDV + 3TC + ABC	ZDV+ 3TC + EFV				
ZDV + 3TC + NFV	ABC + ddI + IDV/r	ZDV + 3TC + SQV/r	ZDV + 3TC + NFV				
ZDV + 3TC + LPV/r							
TDF + 3TC + NVP							
TDF + 3TC + EFV							

Steps in the Quantification

The following approach to quantification is based on the experience of DELIVER advisors who have conducted 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 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 take advantage of new drug formulations and reduced prices.

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 a standardized methodology for forecasting and quantification of all ARV drug requirements for a country or program is recommended—regardless of the source of supply of drugs—to facilitate application of standard treatment guidelines and minimize parallel procurement and distribution systems, 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 needs of the whole country
- Quantifications by health sector (public sector, nongovernmental organizations, or private sector)

- Quantifications by program (for example, national PMTCT or ART programs, PMTCT Plus, pilot ART sites, or other donor-supported ART services)
- Quantifications by target population (for example, highest-prevalence 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 others)
- 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 and how it will address the program's needs must be identified. For example:

- 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 assess the stock status of the in-country supply pipeline to identify and correct supply imbalances?
- 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 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, 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 (for example, adult and pediatric ART, PMTCT, HIV/TB, PEP); the model of care; the program leadership and management system; the standard treatment guidelines for ART; the number and location of ART sites; patient enrollment criteria; and the number of patients currently 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 mobilizing financial resources for procurement of ARV drugs to support program expansion. Quantification and costing of commodity requirements for procurement with available funds for a one-year period is 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 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 on any actual services provided or drugs dispensed, on an assessment of realistic service delivery capacity or supply chain capacity, or 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:

- Current level of service provision (number of sites with trained providers, infrastructure, laboratory services, and 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 national levels)
- Plans for financing and procurement of 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 and 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 the ARV drug supply required to undertake the quantification.

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

- Identify the type of program (for example, ministry of health, nongovermental organization, mission or religious, or pilot or research).
- List all ART services provided (PMTCT; PMTCT Plus; adult, adolescent, and pediatric HAART; HIV/TB; PEP).
- Describe the model of care (level and type of facilities where ART is provided: primary, secondary, tertiary, or community-based).
- Ascertain national ART guidelines, including standard treatment regimens recommended and approved for:
  - 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 drug resistance
  - PMTCT (short-course therapy and single-dose nevirapine regimens for both mother and newborn)
  - Treatment regimens for patients with HIV/TB co-infection
  - PEP (treatment regimens for high-risk and low-risk exposure)
- Verify that all ARV drugs required in the standard treatment guidelines 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:
  - Form and strength (tablet, capsule, oral suspensions, and all dosages available)
  - Single-drug formulations and fixed-dose combination drugs
  - Pediatric formulations
- Identify suppliers for each ARV drug formulation.

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

- 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®).
- Determine the amount and duration of each financial commitment for ARV drug procurement.
- Identify the procurement mechanisms and drug suppliers for each product (national bulk procurement, procurement through local distributors, or direct donation of product).
- Verify local and international pricing information for each presentation of each drug, for generic and brand-name drugs.
- 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 might) the cost to patients affect uptake, recruitment, and retention of patients on ART (important for adherence)?
- 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.
- Verify flexibility in amounts and availability of funding—for example, are there potential funds that can be reallocated for procurement of ARV drugs and how long would reallocation take?

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

- Obtain national- and facility-level logistics data on ARV drug consumption, losses and adjustments, and stock on hand, if available.
- Calculate the wastage rate of ARV drug products caused by expiration, loss, or damage of the products. Without data, this rate is currently assumed to be 5 percent until data from stock cards become available.
- Determine whether an inventory control system is in place for management of ARV drugs.
- Determine procurement lead times and supplier schedules and lead times for delivery of product.
- Determine established buffer stock levels or maximum and minimum inventory levels, if available.
- Confirm facility order intervals.
- Determine the frequency and 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 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, severe rash to NVP)[1].
  - Estimated percentage of patients who will experience treatment failure or develop resistance to one or more of the three drugs in first-line regimen and will require complete regimen change to second-line regimen, and estimated percentage of patients on second-line regimen who will experience side effects or toxicity

1. The estimated percentages of patients who will experience side effects or toxicity are specific for each drug and may also be country 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 or more, or all, of the ARV drugs. For example, a certain percentage of patients will be expected to experience severe skin rash from nevirapine within the initial two weeks of treatment when starting with a lead-in dose of 200 mg/day and will need to switch to efavirenz. Another percentage of patients will be expected to experience this and other toxicities to NVP within the first 6 months of treatment, and yet others, within the first 12 months of treatment. These timeframes within which specific ARV drug changes are expected to occur may be built into the forecast.

to one of the three drugs and 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 (bodyweight 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
  - Estimated percentage of patients who are expected to require PEP (due to high risk and low risk exposure)
  - Default rate, which captures the estimated percentage of patients who will discontinue ART because of dropout attributable to inability to tolerate side effects, nonadherence, loss to follow up, or death within each year of the forecast.

Forecast the Demand

After collecting as much of the data and information as possible, prepare the forecast as follows:

- Document the assumptions made based on the data and information collected and on input from ART stakeholders.
- Using Excel spreadsheets or software designed to calculate the quantities of each ARV drug needed per day or per month—and per year for each ARV drug regimen—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 change ARV drugs 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 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 response to treatment as previously noted. This total is the quantity required to meet expected demand.

See *Annex A. Sample Excel Spreadsheets for Quantification of ARV Drugs* which illustrates how the assumptions for each step of the quantification are captured.

Adjust the Forecast Demand

The quantities of ARV drugs forecast to meet expected demand should be further refined and adjusted, taking into account service delivery capacity according to the number of functioning ART sites, current volume of services, availability and training of personnel, and existing laboratory infrastructure and capacity to support HIV diagnosis and patient monitor-

ing for drug toxicity and viral resistance. An assessment of service delivery capacity will help determine the greatest number of patients who can realistically initiate and continue treatment and 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, constraints in service delivery capacity 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 forecast quantities required 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 the Quantity to Order

At this step in the quantification,[2] an assessment is needed of the supply status within the country in order to calculate the quantities of each ARV drug to be ordered. The quantity to order 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 adjusted forecast of demand *and* to fill the pipeline to ensure continuous supply at ART sites. The quantity to order 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. Arriving at the quantity to order for the next one-year procurement period requires making adjustments to account for lead time, buffer stock, stock on hand, loss and wastage, and quantity on order. (The adjusted quantity to order may be greater or less than the quantity required, depending on current stock on hand and expected consumption rates.) The quantity to order may also need to be further adjusted to reflect current storage and distribution capacity, especially for products that may require refrigeration.

These are the steps:

- Using Excel spreadsheets or software designed to calculate the quantity to order of each ARV drug, enter the total quantity of each ARV drug needed for all uses of the drug within the different treatment regimens to treat the number of patients estimated to be on treatment for the next one-year period.
- Calculate the additional quantity of each ARV drug that will need to be ordered to cover the expected wastage rate due to product expiration, loss, or damage. Wastage rates are currently assumed to be 5 percent of total quantity required until data become available from stock cards.

2. This step and the one in the next section can be completed using Excel spreadsheets, as described, or using the 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 users' manual.

- Divide the total quantity required of each ARV drug by 12 to determine the average monthly quantity required (AMQR).
- 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, allocating and disbursing the funding, contracting suppliers, procuring the products, delivering the shipment, clearing customs, inspecting the products, and receiving the products into the central warehouse.
- 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, assumptions may need to be made about current stock levels.
- 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 *Annex B. Quantity to Order and Cost Estimate* for an example of an Excel spreadsheet used to complete these calculations.

Additional adjustments in the quantity to order may be required at this point in the quantification to reflect the volume of product that can be adequately stored and distributed to ensure the quality and security of the ARV drug supply. By using the DELIVER *ARV Drug Logistics Fact Sheets* 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 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.

For the quantification, it will also be necessary 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.

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 consumption of ARV drugs are not available at the time the quantification is conducted, assumptions may need to be made about national and facility stock levels, lead times for funding disbursement and procurement actions, recommended buffer stocks, and supplier delivery schedules and lead times.

Calculate the Financial Requirements

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 insur-

ance 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 to be procured if it is not included in supplier rates or budgeted for through other mechanisms or waiver agreements.

The steps for calculating the financial requirements are as follows:

- Using Excel spreadsheets or software that is designed to calculate the cost of the quantity to order of each ARV drug presentation, 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.
- Enter the pack size for each ARV drug presentation. The pack size is the number of basic units of the drug per smallest unit of supplier packaging (e.g., 60 tablets of NVP 200 mg per bottle).
- Adjust the quantity to order by dividing the total number of basic units by pack size and rounding up the quantity to order to the nearest whole unit of supplier packaging.
- Using 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.

See *Annex B. Quantity to Order and Cost Estimate* for an example of an Excel spreadsheet 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 used for calculating the cost of the quantity to order for each drug may be used with different supplier rates and costs per pack to arrive at alternate total cost scenarios to be considered when making decisions on funding sources and allocations for procurement.

Compare the Cost to Available Funding and Determine the Quantity to Procure

The final decision on the quantities to procure will be determined by the amount of funding available for procurement of ARV drugs. If sufficient funding is available, the final quantity to procure of each ARV drug will be the same as the quantity to order arrived at by the quantification. 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 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 to secure future sources of financing to continue procurement of ARVs for patients already on treatment and to expand ART services to reach more people.

In situations of non-full supply, in which funding is insufficient to procure the quantities of ARV drugs needed, the number of patients who can be expected to initiate ART within the period of the forecast—and therefore the quantities of ARV drugs required—will need to be reduced. The findings, methodology, and assumptions made in the quantification should be reviewed with ART stakeholders to come to 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. The priority for funding and procurement of ARV drugs should be to maintain the ARV drug supply for patients already on ART.

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 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 that could initiate and continue ART for a year.

After the annual quantity to procure has been determined, a flexible shipment schedule is recommended—often quarterly—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

The complexity and level of detail required to be able to forecast the quantities of pediatric ARV drugs needed for a specific number of patients reflect the general complexity and sophistication required for diagnosis, care, and treatment of pediatric ART patients. Key factors that influence and complicate the provision of pediatric ART include the following:

- Prescribing and dispensing of pediatric ARV drugs is complicated by the 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 tablet formulations need to be cut or crushed to meet pediatric dosages.
- Patient adherence is difficult because of complicated dosing, large volumes, and foul taste of liquid formulations as well as children's inability to swallow pills.
- Selection and availability of ARV drugs for children are limited; for example, no fixed-dose combinations 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.

The following are challenges specific to the quantification of pediatric ARV drug requirements:

- Calculating the number of pediatric patients expected to initiate ART during the period of the forecast. This number may be based on the number of the children estimated to be on ART as a proportion of the total number of patients on ART for the forecast year, or, if data are available, 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).
- Using liquid, tablet, and capsule formulations.
- Using adult tablets (cut or crushed to meet pediatric dosages).
- Calculating pediatric dosages by age, weight band, and body surface area.

- Capturing changes in dosages and formulations as children grow. The greatest challenge in estimating the percentages of children who will be within a specific weight band and who will require specific dosages of pediatric formulations during the forecast year has been how to capture the change in dosages and in formulations (liquids to capsules or tablets) over time as children grow, and to incorporate the changing needs of the cohort of existing pediatric patients as they move from year to year of treatment.
- Applying a phase-in rate to capture the gradual increase in the number of pediatric patients on ART over the period of the forecast.
- Using a default rate to capture pediatric patients who may discontinue treatment during the period of the forecast.
- Calculating the high wastage rate caused by the short shelf life and large volume of liquid formulations. If data are available, 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, determined by consultation with informed stakeholders.
- Calculating 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. Include the calculations of available storage space in-country and compare them with the volume of incoming shipments of pediatric formulations to be procured that require maintainance of the cold chain in storage and transport.

Annex A

Sample Excel Spreadsheets for Quantification of ARV Drugs

Patient Targets

	Assumptions	2005	2006	2007
Total Population	103%	10,300,000	10,598,700	10,906,062
Population in reproductive age group (15–60 yrs)	49%	5,047,000	5,193,363	5,343,971
Pediatric population (0–14 yrs)	47%	4,789,500	4,928,396	5,071,319
National HIV prevalence	16%			
Total PLWHA		1,000,000	1,000,000	1,000,000
Total AIDS cases clinically eligible for ART	20%	200,000	200,000	200,000
Adult AIDS cases eligible for and accessing ART	85%	170,000	170,000	170,000
Pediatric AIDS cases eligible for and accessing ART	15%	30,000	30,000	30,000
Patient Targets from WHO 3x5 scale-up plan	50%	100,000		
TOTAL TARGETS FOR TREATMENT		**25,000**	**45,000**	**100,000**

TOTAL PATIENTS 2005

Total No. Patients	**25,000**
Percent on first-line regimens	95%
Percent on second-line regimens	5%
Percent Adults	95%
Percent Children	5%

# Adults on first-line regimens	22,563
# Adults on second-line regimens	1,188
# Children on first-line regimens	1,188
# Children on second-line regimens	63

# HIV positive mothers on PMTCT	46,000
# Infants on PMTCT	46,000

# PMTCT mothers on NVP/labor	46,000
# PMTCT mothers on AZT	—
# PMTCT infants	46,000

TOTAL PATIENTS 2006

Total No. Patients	**45,000**
Percent on first-line regimens	93%
Percent on second-line regimens	7%
Percent Adults	95%
Percent Children	5%

# Adults on first-line regimens	39,758
# Adults on second-line regimens	2,993
# Children on first-line regimens	2,093
# Children on second-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

Total No. Patients	**100,000**
Percent on first-line regimens	90%
Percent on second-line regimens	10%
Percent Adults	90%
Percent Children	10%

# Adults on first-line regimens	81,000
# Adults on second-line regimens	9,000
# Children on first-line regimens	9,000
# Children on second-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

PMTCT	**2004**	**2005**	**2006**	**2007**
New ANC attendees	9,403	10,000	15,000	20,000
Pregnant women tested (%)	30%	50%	75%	95%
#Pregnant woment tested	2,821	5,000	11,250	19,000
#Pregnant women positive (eligible for prophylaxis)	451	800	1,800	3,040

ADULT REGIMENS YEAR 2005

YEAR 2005	Percent	No. Patients
Total No. Patients	**100%**	**25,000**
Percent on first-line regimen	95%	22,563
Percent on second-line regimen	5%	1,188
Percent Adults	95%	23,750
Percent Children	5%	1,250

Options	First-line Regimens (Adults)	Percent	No. Patients
	Total No. Patients	**100%**	**22,563**
A1	d4T (30mg)/3TC/NVP	25%	5,641
A2	d4T (40mg)/3TC/NVP	20%	4,513
B	(AZT/3TC+NVP) Aspen co-pack	42%	9,476
C1	d4t (30mg)/3TC+EFV	5%	1,128
C2	d4t (40mg)/3TC+EFV	5%	1,128
D	AZT/3TC+EFV	3%	677

Options	Second-line Regimens (Adults)	Percent	No. Patients
	Total No. Patients	**100%**	**1,188**
E1	TDF + ddI + LPV/r < 60kg	23%	273
E2	TDF + ddI + LPV/r > 60kg	23%	273
F1	TDF + ddI + NFV < 60kg	23%	273
F2	TDF + ddI + NFV > 60kg	23%	273
G1	ABC + ddI + LPV/r < 60kg	1%	12
G2	ABC + ddI + LPV/r >60kg	1%	12
H1	TDF + ddI + SQV/r < 60kg	3.0%	36
H2	TDF + ddI + SQV/r > 60kg	3.0%	36

Options	PMTCT Prophylaxis (Mother)	Percent	No. Patients
	Total No. Patients	**100%**	**46,000**
M	AZT 300mg bd/6 weeks	0%	0
N	Nevirapine 200mg at labor	100%	46,000

ADULT REGIMENS YEAR 2005
PHASING-IN RATES

FIRST-LINE REGIMENS

Phasing-In by %	%	# Days	Patients	Patient-days
Quarter 1	15%	365	3,384.38	1,235,297
Quarter 2	20%	275	4,512.50	1,240,938
Quarter 3	30%	184	6,768.75	1,245,450
Quarter 4	35%	92	7,896.88	726,513
	100%		**22,563**	**4,448,197**

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

SECOND-LINE REGIMENS

Phasing-In by %	%	# Days	Patients	Patient-days
Quarter 1	5%	365	59.38	21,672
Quarter 2	10%	275	118.75	32,656
Quarter 3	25%	184	296.88	54,625
Quarter 4	60%	92	713	65,550
	100%		**1,188**	**174,503**

Total patient-days covered	174,503
Total possible patient-days	433,438
% total patient-days covered	40.26%

ADULT REGIMENS YEAR 2006

YEAR 2006	Percent	No. Patients
Total No. Patients	**100%**	**45,000**
Percent on first-line regimen	93%	39,758
Percent on second-line regimen	7%	2,993
Percent Adults	95%	42,750
Percent Children	5%	2,250

Options	First-line Regimens (Adults)	Percent	No. Patients	New Patients
	Total No. Patients	**100%**	**39,758**	
A1	d4T (30mg)/3TC/NVP	28%	11,132	5,491
A2	d4T (40mg)/3TC/NVP	25%	9,939	5,427
B	(AZT/3TC+NVP) Aspen co-pack	34%	13,518	4,041
C1	d4t (30mg)/3TC+EFV	5%	1,988	860
C2	d4t (40mg)/3TC+EFV	5%	1,988	860
D	AZT/3TC+EFV	3%	1,193	516
				17,195

Options	Second-line Regimens (Adults)	Percent	No. Patients	New Patients
	Total No. Patients	**100%**	**2,993**	
E1	TDF + ddI + LPV/r < 60kg	23%	688	415
E2	TDF + ddI + LPV/r > 60kg	25%	748	475
F1	TDF + ddI + NFV < 60kg	23%	688	415
F2	TDF + ddI + NFV > 60kg	25%	748	475
G1	ABC + ddI + LPV/r < 60kg	1%	15	3
G2	ABC + ddI + LPV/r >60kg	1%	15	3
H1	TDF + ddI + SQV/r < 60kg	1.5%	45	9
H2	TDF + ddI + SQV/r > 60kg	1.5%	45	9
				1,805

Options	PMTCT Prophylaxis	Percent	No. Patients
		100%	**56,000**
M	AZT 300mg bd/6 weeks	50%	28,000
N	Nevirapine 200mg at labor	50%	28,000

ADULT REGIMENS YEAR 2006
PHASING-IN RATES

FIRST-LINE REGIMENS		Existing Pts (Year 2005)	New Pts.	Total New (New + Default)
Phasing-in first-line regimens		22,563	17,195	18,323
Default Rate first-line regimens	5%	1,128		

Phasing-in of New Patients on First-line Regimens

Phasing-In by %	%	# Days	Patients	Patient-days
Quarter 1	25%	365	4,581	1,671,985
Quarter 2	25%	275	4,581	1,259,715
Quarter 3	25%	184	4,581	842,864
Quarter 4	25%	92	4,581	421,432
Total			**18,323**	**4,195,996**

SECOND-LINE REGIMENS		Existing Pts. (Year 2005)	New Pts.	Total New (New + Default)
Phasing-in second-line regimens		1,188	1,805	1,864
Default Rate second-line regimens	5%	59		

Phasing-in of New Patients on Second-line regimens

Phasing-In by %	%	# Days	Patients	Patient-days
Quarter 1	15%	365	280	102,075
Quarter 2	20%	275	373	102,541
Quarter 3	30%	184	559	102,914
Quarter 4	35%	92	653	60,033
Total			**1,864**	**367,562**

PMTCT Prophylaxis	%	# Days	No. Patients	Patient-days
Total No. Patients	**100%**		**56,000**	
AZT 300mg bid/ 6 weeks	50%	42	28,000	1,176,000
NVP 200mg at labor	50%	1	28,000	28,000

ADULT REGIMENS YEAR 2007

YEAR 2007	Percent	No. Patients
Total No. Patients	**100%**	**100,000**
Percent on first-line regimen	90%	81,000
Percent on second-line regimen	10%	9,000
Percent Adults	90%	90,000
Percent Children	10%	10,000

Options	First-line Regimens (Adults)	Percent	No. Patients	New Patients
	Total No. Patients	**100%**	**81,000**	
A1	d4T (30mg)/3TC/NVP	28%	22,680	11,548
A2	d4T (40mg)/3TC/NVP	29%	23,490	13,551
B	(AZT/3TC + NVP) Aspen co-pack	30%	24,300	10,782
C1	d4t (30mg)/3TC + EFV	5%	4,050	2,062
C2	d4t (40mg)/3TC + EFV	5%	4,050	2,062
D	AZT/3TC + EFV	3%	2,430	1,237
				41,243

Options	Second-line Regimens (Adults)	Percent	No. Patients	NewPatients
	Total No. Patients	**100%**	**9,000**	
E1	TDF + ddI + LPV/r < 60kg	23%	2,070	1,382
E2	TDF + ddI + LPV/r > 60kg	26%	2,340	1,592
F1	TDF + ddI + NFV < 60kg	23%	2,070	1,382
F2	TDF + ddI + NFV > 60kg	26%	2,340	1,592
G1	ABC + ddI + LPV/r < 60kg	0.5%	45	30
G2	ABC + ddI + LPV/r >60kg	0.5%	45	30
H1	TDF + ddI + SQV/r < 60kg	0.5%	45	0
H2	TDF + ddI + SQV/r > 60kg	0.5%	45	0
				6,008

Options	PMTCT Prophylaxis	Percent	No. Patients
		100%	76,000
M	AZT 300mg bd/6 weeks (42 days)	50%	38,000
N	Nevirapine 200 mg at labour	50%	38,000

ADULT REGIMENS YEAR 2007
PHASING-IN RATES

FIRST-LINE REGIMENS	Percent	Existing Patients (Year 2006)	New Patients	Total New (New + Default)
Phasing-in first-line		39,758	41,243	43,230
Default Rate first-line	5%	1,988		

Phasing-in of New Patients on First-line Regimens

Phasing-In by %	%	# Days	Patients	Patient-days
Quarter 1	25%	365	10,808	3,944,772
Quarter 2	25%	275	10,808	2,972,088
Quarter 3	25%	184	10,808	1,988,597
Quarter 4	25%	92	10,808	994,299
Total				**9,899,756**

SECOND-LINE REGIMENS	Percent	Existing Patients (Year 2006)	New Patients	Total New (New + Default)
Phasing-in second-line		2,993	6,008	6,157
Default Rate second-line	5%	150		

Phasing-in of New Patients on Second-line Regimens

Phasing-In by %	%	# Days	Patients	Patient-days
Quarter 1	15%	365	924	337,103
Quarter 2	25%	275	1,539	423,302
Quarter 3	25%	184	1,539	283,228
Quarter 4	35%	92	2,155	198,259

PMTCT Prophylaxis	%	# Days	No. Patients	Patient-days
Total No. Patients			**76,000**	
AZT 300mg bd X 6 weeks (42 days)	50%	42	38,000	1,596,000
NVP 200mg at labor	50%	1	38,000	38,000

QUALITY REQUIRED (ADULTS) Forecast Years 2005–2007

		YEAR 2005				YEAR 2006				YEAR 2007			
Option	**REGIMENS**	**No. Patients**	**Patient-days**	**Units per Patient-day**	**No. Basic Units Required**	**No. Patients**	**Patient-days**	**Units per Patient-day**	**No. Basic Units Required**	**No. Patients**	**Patient-days**	**Units per Patient-day**	**No. Basic Units Required**
	First-line Regimens (Adults)												
A1	d4T (30mg)+3TC+NVP	5,641	1,112,049	2	2,224,098	11,132	3,316,376	2	6,632,752	22,680	6,707,686	2	13,415,371
A1	3TC/d4T (30)		84,609	2	169,219		82,372	2	164,744		173,219	2	346,437
A1	NVP (Nevirapine) 200mg			1	84,609			1	82,372			1	173,219
A2	d4T (40mg)+3TC+NVP	4,513	889,639	2	1,779,279	9,939	2,889,817	2	5,779,634	23,490	6,730,965	2	13,461,930
A2	d4T (40)/3TC		67,688	2	135,375		81,403	2	162,806		203,259	2	406,519
A2	NVP (Nevirapine) 200 mg			1	67,688			1	81,403			1	203,259
B	(AZT/3TC + NVP) Aspen co-pack	9,476	1,868,243	2	3,736,485	13,518	4,384,289	2	8,768,578	24,300	7,403,087	2	14,806,174
C1	d4t (30mg)/3TC	1,128	222,410	2	444,820	1,988	608,648	2	1,217,297	4,050	1,197,801	2	2,395,602
C1	EFV 600mg			1	222,410			1	608,648			1	1,197,801
C2	d4T (40)/3TC	1,128	222,410	2	444,820	1,988	608,648	2	1,217,297	4,050	1,197,801	2	2,395,602
C2	EFV 600mg			1	222,410			1	608,648			1	1,197,801
D	AZT/3TC from Aspen co-pack	677	133,446	2	266,892	1,193	365,189	2	730,378	2,430	718,681	2	1,437,361
D	EFV 600mg			1	133,446			1	365,189			1	718,681

QUALITY REQUIRED (ADULTS) Forecast Years 2005–2007 *continued*

		YEAR 2005				YEAR 2006				YEAR 2007			
Option	**REGIMENS**	**No. Patients**	**Patient-days**	**Units per Patient-day**	**No. Basic Units Required**	**No. Patients**	**Patient-days**	**Units per Patient-day**	**No. Basic Units Required**	**No. Patients**	**Patient-days**	**Units per Patient-day**	**No. Basic Units Required**
	< 60 kg												
E	Tenofovir 300mg	273	40,136	1	40,136	688	181,537	1	181,537	2,070	529,914	1	529,914
E	Didanosine 200mg			1	40,136			1	181,537			1	529,914
E	Didanosine 25mg			2	80,271			2	363,075			2	1,059,829
E	LPV/r 133/33mg			6	240,814			6	1,089,225			6	3,179,486
	> 60 kg												
F	Tenofovir 300mg	273	40,136	1	40,136	748	193,337	1	193,337	2,340	594,147	1	594,147
F	Didanosine 200mg			2	80,271			2	386,674			2	1,188,294
F	LPV/r 133/33mg			6	240,814			6	1,160,021			6	3,564,881
	< 60 kg												
G	Tenofovir 300mg	273	40,136	2	80,271	688	181,537	2	363,075	2,070	529,914	2	1,059,829
G	ddI (Didanosine) 200mg			1	40,136			1	181,537			1	529,914
G	ddI (Didanosine) 25mg			2	80,271			2	363,075			2	1,059,829
G	Nelfinavir 625 mg			4	160,543			4	726,150			4	2,119,657
	> 60 kg												
H	Tenofovir 300mg	273	40,136	2	80,271	748	193,337	2	386,674	2,340	594,147	2	1,188,294
H	ddI (Didanosine) 200mg			2	80,271			2	386,674			2	1,188,294
H	Nelfinavir 625 mg			4	160,543			4	773,348			4	2,376,587

QUALITY REQUIRED (ADULTS) Forecast Years 2005–2007 *continued*

		YEAR 2005				YEAR 2006				YEAR 2007			
Option	**REGIMENS**	**No. Patients**	**Patient-days**	**Units per Patient-day**	**No. Basic Units Required**	**No. Patients**	**Patient-days**	**Units per Patient-day**	**No. Basic Units Required**	**No. Patients**	**Patient-days**	**Units per Patient-day**	**No. Basic Units Required**
I	ABC (Abacavir) 300mg	12	1,745	1	1,745	15	5,461	1	5,461	45	16,425	1	16,425
I	ddI (Didanosine) 200mg			1	1,745			1	5,461			1	16,425
I	ddI (Didanosine) 25mg			2	3,490			2	10,923			2	32,850
I	LPV/r 133/33mg			10	17,450			10	54,613			10	164,250
	> 60 kg												
J	ABC (Abacavir) 300mg	12	1,745	1	1,745	15	5,461	1	5,461	45	16,425	1	16,425
J	ddI (Didanosine) 200mg			2	3,490			2	10,923			2	32,850
J	LPV/r 133/33mg			10	17,450			10	54,613			10	164,250
	< 60 kg												
K	Tenofovir 300mg	36	5,235	2	10,470	45	16,384	2	32,768	45	16,425	2	32,850
K	ddI (Didanosine) 200mg			1	5,235			1	16,384			1	16,425
K	ddI (Didanosine) 25mg			2	10,470			2	32,768			2	32,850
K	SQV (Saquinivir) 200mg			10	52,351			10	163,839			10	164,250
K	R (Ritonavir) 100mg			2	10,470			2	32,768			2	32,850
	> 60 kg												
L	Tenofovir 300mg	36	5,235	2	10,470	45	16,384	2	32,768	45	16,425	2	32,850
L	ddI (Didanosine) 200mg			2	10,470			2	32,768			2	32,850
L	SQV (Saquinivir) 200mg			10	52,351			10	163,839			10	164,250
L	R (Ritonavir) 100mg			2	10,470			2	32,768			2	32,850
	PMTCT Prophylaxis	46,000											
M	AZT 300mg	46,000	0	2	0	28,000	1,176,000	2	2,352,000	38,000	1,596,000	2	3,192,000
N	Nevirapine 200mg tablet	46,000	46,000	1	46,000	28,000	28,000	1	28,000	38,000	38,000	1	38,000

PEDIATRIC REGIMENS YEAR 2005

Options	First-line Regimens (Children)	Percent	No. Patients
	Total No. Patients	**100%**	**1,188**
	Percentage under 3 years, <12kg		70%
P1	AZT+3TC+NVP	50%	416
P2	d4T+3TC+NVP	50%	416
	Percentage >3–12 yrs, 12–30kg		30%
P3	(AZT/3TC+NVP) Aspen co-pack	60%	214
P4	d4T30/3TC/NVP	20%	71
P5	d4T30/3TC+EFV	20%	71

Options	Second-line Regimens (Children)	Percent	No. Patients
	Total No. Patients	**100%**	**63**
	Percentage <12kg		10%
P6	ABC+3TC+NFV	100%	6
	Percentage 12–30kg (tabs)		85%
P7	ABC+3TC+LPV/r	70%	37
P8	ABC+3TC+NFV	30%	16
	Percentage 12–30kg (susp)		5%
P9	ABC+3TC+LPV/r	70%	2
P10	ABC+3TC+NFV	30%	1

Option	PMTCT Prophylaxis (Infants)	Percent	No. Patients
	Total No. Patients	**100%**	**46,000**
Q	Infants 5mg Nevirapine (susp)	100%	46,000
R	Infants on AZT syrup	0%	0

PEDIATRIC REGIMENS YEAR 2005

FIRST-LINE REGIMENS

Phasing-In by %	%	# Days	Patients	Patient-days
Quarter 1	10%	365	118.75	43,344
Quarter 2	15%	275	178.13	48,984
Quarter 3	30%	184	356.25	65,550
Quarter 4	45%	92	534.38	49,163
	100%		**1,188**	**207,041**

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

SECOND-LINE REGIMENS

Phasing-In by %	%	# Days	Patients	Patient-days
Quarter 1	5%	365	3	1,141
Quarter 2	10%	275	6	1,719
Quarter 3	25%	184	16	2,875
Quarter 4	60%	92	38	3,450
	100%		**63**	**9,184**

Total patient-days covered	9,184
Total possible patient-days	22,813
% total patient-days covered	40.26%

PEDIATRIC REGIMENS YEAR 2006

Options	First-line Regimens (Children)	Percent	No. Patients	New Patients
	Total No. Patients		**2,093**	
	Percentage under 3 years, <12kg		70%	
P1	AZT+3TC+NVP	50%	732	317
P2	d4T+3TC+NVP	50%	732	317
	Percentage >3–12 yrs, 12–30kg		30%	
P3	(AZT/3TC+NVP) Aspen co-pack	60%	377	163
P4	d4T30/3TC/NVP	20%	126	54
P5	d4T30/3TC+EFV	20%	126	54

Options	Second-line Regimens (Children)	Percent	No. Patients	New Patients
	Total No. Patients		**158**	
	Percentage <12kg		10%	
P6	ABC+3TC+NFV	100%	16	10
	Percentage 12–30 kg (tabs)		85%	
P7	ABC+3TC+LPV/r	70%	94	57
P8	ABC+3TC+NFV	30%	40	24
	Percentage 12–30 kg (susp)		5%	
P9	ABC+3TC+LPV/r	70%	6	3
P10	ABC+3TC+NFV	30%	2	1

Option	PMTCT Prophylaxis (Infants)	Percent	No. Patients
	Total No. Patients	**100%**	**56,000**
Q	Infants 5mg Nevirapine (susp)	50%	28,000
R	Infants on AZT syrup	50%	28,000

PEDIATRIC REGIMENS YEAR 2006

Phasing-in Rate for New Patients, by Regimen

Phasing-in by Regimen	Existing Patients	New Patients
First-line regimens	1,188	905
Second-line regimens	63	95

FIRST-LINE REGIMENS

Phasing-in by %	%	# Days	Patients	Patient-days
Quarter 1	25%	365	226	82,581
Quarter 2	25%	275	226	62,219
Quarter 3	25%	184	226	41,630
Quarter 4	25%	92	226	20,815
	100%		**905**	**207,245**

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

SECOND-LINE REGIMENS

Phasing-in by %	%	# Days	Patients	Patient-days
Quarter 1	25%	365	24	8,669
Quarter 2	25%	275	24	6,531
Quarter 3	25%	184	24	4,370
Quarter 4	25%	92	24	2,185
	100%		**95**	**21,755**

Total patient-days covered	21,755
Total possible patient-days	34,675
% total patient-days covered	62.74%

PEDIATRIC REGIMENS YEAR 2007

Options	First-line Regimens (Children)	Percent	No. Patients	New Patients
	Total No. Patients		**9,000**	
	Percentage under 3 years, <12kg		70%	
P1	AZT+3TC+NVP	50%	3,150	2,833
P2	d4T+3TC+NVP	50%	3,150	2,833
	Percentage >3–12, 12–30kg		30%	
P3	(AZT/3TC+NVP) Aspen co-pack	60%	1,620	1,457
P4	d4T30/3TC/NVP	20%	540	486
P5	d4T30/3TC+EFV	20%	540	486

Options	Second-line Regimens (Children)	Percent	No. Patients	New Patients
	Total No. Patients		**1,000**	
	Percentage <12kg		10%	
P6	ABC+3TC+NFV	100%	100	91
	Percentage 12–30 kg tabs		85%	
P7	ABC+3TC+LPV/r	70%	595	538
P8	ABC+3TC+NFV	30%	255	231
	Percentage 12–30kg (susp)		5%	
P9	ABC+3TC+LPV/r	70%	35	32
P10	ABC+3TC+NFV	30%	15	14

Option	PMTCT Prophylaxis (Infants)	Percent	No. Patients
	Total No. Patients	**100%**	**76,000**
Q	Infants 5mg Nevirapine (susp)	50%	38,000
R	Infants on AZT syrup	50%	38,000

PEDIATRIC REGIMENS YEAR 2007

Phasing-In Rate for New Patients, by Regimen

Phasing-in by Regimen	Existing Patients	New Patients
First-line regimens	2,093	6,908
Second-line regimens	158	843

FIRST-LINE REGIMENS

Phasing-in by %	%	# days	Patients	Patient-days
Quarter 1	25%	365	1,727	630,309
Quarter 2	25%	275	1,727	474,891
Quarter 3	25%	184	1,727	317,745
Quarter 4	25%	92	1,727	158,873
	100%		**6,908**	**1,581,818**

Total patient-days covered	1,581,818
Total possible patient-days	2,521,238
% total patient-days covered	62.74%

SECOND-LINE REGIMENS

Phasing-in by %	%	# days	Patients	Patient-days
Quarter 1	25%	365	211	76,878
Quarter 2	25%	275	211	57,922
Quarter 3	25%	184	211	38,755
Quarter 4	25%	92	211	19,378
	100%		**843**	**192,933**

Total patient-days covered	192,933
Total possible patient-days	307,513
% total patient-days covered	62.74%

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
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

		YEAR 2005							YEAR 2006							YEAR 2007						
Option	First-lLine Regimens	Total Patients	Patient-days	Patient-months	Units per Patient-day	Bottles per Patient-month	Total Units /tabs/ caps	Bottles per Year	Total Patients	Patient-days	Patient-months	Units per Patient-day	Bottles per Patient-month	Total Units /tabs/ caps	Bottles per Year	Total Patients	Patient-days	Patient-months	Units per Patient-day	Bottles per Patient-month	Total Units /tabs/ caps	Bottles per Year
	Under 3yrs, <12 kg																					
P1	AZT syrup 10mg/ml	416	72,464	2,415		4		9,662	732	224,239	7,475		4		29,899	3,150	916,131	30,538		4		122,151
	3TC syrup 10mg/ml					3		7,246					3		22,424					3		91,613
	NVP syrup 10mg/ml					3		7,246					3		22,424					3		91,613
	Under 3yrs, <12 kg																					
P2	d4T syrup 1mg/ml powder for syrup	416	72,464	2,415		5		12,077	732	224,239	7,475		5		37,373	3,150	916,131	30,538		5		152,689
	3TC syrup 10mg/ml					3		7,246					3		22,424					3		91,613
	NVP syrup 10mg/ml					3		7,246					3		22,424					3		91,613
	Over 3–12yrs, 12–30 kg																					
P3	(AZT/3TC + NVP) Aspen co-pack	214	37,267		1		37,267		377	115,323		1		115,323		1,620	471,153		1		471,153	
P4	d4T/3TC/NVP (30mg)	71	12,422		1		12,422		126	38,441		1		38,441		540	157,051		1		157,051	
P5	d4T/3TC (30mg)	71	12,422		1		12,422		126	38,441		1		38,441		540	157,051		1		157,051	
	EFV 50mg cap				3		37,267					3		115,323					3		471,153	
	Second-line Regimens																					
	Under 3yrs, <12 kg																					
P6	ABC+3TC+NFV																					
	ABC 20mg/ml oral solution	6	918	31		2		61	16	4,457	149		2		297	100	26,473	882		2		1,765
	3TC 10mg/ml susp 240ml bottle	6	918			2		61	16	4,457			2		297	100	26,473			2		1,765
	NFV 50mg/g powder for susp;144g	6	918			8		245	16	4,457			8		1,188	100	26,473			8		7,060

QUANTITY REQUIRED (CHILDREN) FORECAST YEARS 2005– 2007 *continued*

		YEAR 2005							YEAR 2006							YEAR 2007						
Option	Second-line Regimens	Total Patients	Patient-days	Patient-months	Units per Patient-day	Bottles per Patient-month	Total Units /tabs/ caps	Bottles per Year	Total Patients	Patient-days	Patient-months	Units per Patient-day	Bottles per Patient-month	Total Units /tabs/ caps	Bottles per Year	Total Patients	Patient-days	Patient-months	Units per Patient-day	Bottles per Patient-month	Total Units /tabs/caps	Bottles per Year
	12-30 kg (tabs)																					
P7	ABC+3TC+ LPV/r																					
	ABC 300mg tablet	37	5,465		2		10,929		94	26,518		2		53,035		595	157,516		2		315,032	
	3TC 150 mg tablet	37	5,465		2		10,929		94	26,518		2		53,035		595	157,516		2		315,032	
	LPV/r 133.3/33.3 caps	37	5,465		14		76,506		94	26,518		14		371,247		595	157,516		14		2,205,222	
P8	ABC+3TC+NFV																					
	ABC 300mg tablet	16	2,342		2		4,684		40	11,365		2		22,729		255	67,507		2		135,014	
	3TC 150 mg tablet	16	2,342		2		4,684		40	11,365		2		22,729		255	67,507		2		135,014	
	NFV/r 250mg tab	16	2,342		4		9,368		40	11,365		4		45,459		255	67,507		4		270,027	
	12–30 kg (susp)																					
P9	ABC+3TC+NFV																					
	ABC 20mg/ml oral susp	1	138	5		2	–	9	2	1,104	37		2	–	74	15	8,116	271		2		541
	3TC 10mg/ml susp 240ml bottle	1	138	5		3		14	2	1,104	37		3		110	15	8,116	271		3		812
	NFV 50mg/g powdwe for susp;144g	1	138	5		8		37	2	1,104	37		8		294	15	8,116	271		8		2,164
P10	ABC+3TC+ LPV/r																					
	ABC 20mg/ml oral solution	2	321	11		2		21	6	1,125	37		2		75	35	5,121	171		2		341
	3TC 10mg/ml susp 240ml bottle	2	321	11		3		32	6	1,125	37		3		112	35	5,121	171		3		512
	LPV/r 20mg/ 80mg/ml	2	321	11		1		11	6	1,125	37		1		37	35	5,121	171		1		171
	PMTCT Prophylaxis (Infants)																					
Q	NVP 10mg/1ml oral susp 240 ml bottle	46,000	46,000		1			144	28,000	28,000		0.5			87.5	38,000			0.5			119
R	AZT syrup 200 ml/bottle								28,000	28,000			1		28,000	38,000				1		38,000

FORECAST QUANTITIES 2005–2007

DRUG PRODUCT	Basic Unit	Total No. Basic Units Required 2005	Total No. Basic Units Required 2006	Total No. Basic Units Required 2007
FIRST-LINE REGIMEN DRUGS				
d4T (30mg)/3TC/NVP	tablet	2,224,098	6,632,752	13,415,371
TOTAL ADULT + PEDIATRIC		2,236,521	6,671,193	13,572,422
d4T(30)/3TC	tablet	614,038	1,382,041	2,742,039
TOTAL ADULT + PEDIATRIC		626,461	1,420,482	2,899,090
d4T(40mg)/3TC/NVP	tablet	1,779,279	5,779,634	13,461,930
d4T(40)/3TC	tablet	580,195	1,380,103	2,802,121
(AZT/3TC + NVP) Aspen co-pack	tablet	4,003,377	9,498,956	16,243,535
TOTAL ADULT + PEDIATRIC		4,040,645	9,614,279	16,714,688
EFV 600mg	capsule	578,266	1,582,486	3,114,283
AZT 300mg	tablet	0	2,352,000	3,192,000
SECOND-LINE REGIMEN DRUGS				
Tenofovir 300mg	tablet	261,755	1,190,159	3,437,883
Didanosine 200mg	tablet	261,755	1,201,958	3,534,966
Didanosine 25mg	tablet	174,503	769,840	2,185,357
LPV/r 133/33mg	capsule	516,529	2,358,472	7,072,867
TOTAL ADULT + PEDIATRIC		593,035	2,729,719	9,278,088
NFV 625mg	tablet	321,086	1,499,497	4,496,244
ABC (Abacavir) 300mg	tablet	3,490	10,923	32,850
TOTAL ADULT + PEDIATRIC		19,104	86,687	482,895
SQV (Saquinavir) 200mg	capsule	104,702	327,679	328,500
R (Ritonavir) 100mg	tablet	20,940	65,536	65,700

FORECAST QUANTITIES 2005–2007 *continued*

DRUG PRODUCT	Basic Unit	Total No. Basic Units Required 2005	Total No. Basic Units Required 2006	Total No. Basic Units Required 2007
PEDIATRIC FIRST- AND SECOND-LINE DRUGS				
AZT syrup 10mg/ml	bottle	9,662	57,899	160,151
3TC syrup 10mg/ml	bottle	14,600	45,368	186,315
NVP syrup 10mg/ml	bottle	14,637	44,935	183,345
d4T syrup 10mg/ml	bottle	12,077	37,373	152,689
(AZT/3TC + NVP) Aspen co-pack	tablet	37,267	115,323	471,153
d4T(30mg)/3TC/NVP	tablet	12,422	38,441	157,051
d4T(30mg)/3TC	tablet	12,422	38,441	157,051
EFV 50mg cap	capsule	37,267	115,323	471,153
ABC 20mg/ml oral solution	bottle	92	446	2,647
NFV 50mg/g powder for susp;144g	bottle	282	1,483	9,224
ABC 300mg tablet	tablet	15,613	75,765	450,045
3TC 150 mg tablet	tablet	15,613	75,765	450,045
LPV/r 133.3/33.3 caps	capsule	76,506	371,247	2,205,222
NFV 250mg tab	tablet	9,368	45,459	270,027
LPV/r 20mg/80mg/ml (1 unit = 5 x 60ml bottles)	bottle	11	37	171

Annex B

Quantity to Order and Cost Estimate

NATIONAL ART PROGRAM: ARV DRUG REQUIREMENTS FORECAST YEAR 2005

No.	Drug Product	Basic Unit	QUANTITY TO ORDER							Issue Pack Size	COST ESTIMATE			
			Quantity Required	Adusted QR	AMQR	DEOYS	SOH	Quantity on Order	Annual QO		Quantity to Order	COST Generic	COST Branded	
			Total No. Basic Units	Losses/ Wastage 5%	Average Monthly QR	AMQR x (11 months) DEOYS	Usable Stock on Hand	Quantity on Order (No. Units)	Quantity to Order (No. Units)		Rounded to Pack Size	Cost/ Pack Size US$	Cost/ Pack Size US$	TOTAL COST US$
1.	AZT/3TC (Zidovudine/ Lamivudine) 300mg/ 150mg	Tablet	2,724,517	2,860,743	238,396	2,622,356			2,622,356	60	43,706	$0.270	$0.325	
2.	NVP (Nevirapine) 200mg	Tablet	1,966,329	2,064,645	172,054	1,892,594			1,892,594	60	31,544	$0.110	$0.600	
3.	EFV (Efavirenz) 200mg capsule	Capsule	86,388	90,708	7,559	83,149			83,149	90	924	$0.300	$0.457	
4.	EFV (Efavirenz) 600mg	Tablet	1,014,469	1,065,193	88,767	976,437			976,437	30	32,548	$0.950	$0.950	
5.	Zidovudine (AZT) 300mg	Tablet	0	0	0	0			0	60	0	$0.192	$0.290	
6.	3TC (Lamivudine) 150 mg	Tablet	1,417,477	1,488,351	124,030	1,364,330			1,364,330	60	22,739	$0.075	$0.095	
7.	d4T (Stavudine) 30mg	Capsule	1,212,085	1,272,689	106,058	1,166,638			1,166,638	60	19,444	$0.029	$0.066	
8.	d4T (Stavudine) 40mg	Capsule	155,848	163,640	13,637	150,007			150,007	60	2,501	$0.035	$0.075	
9.	ddI (Didanosine) 150mg	Tablet	10,950	11,498	959	10,549			10,549	60	176	$–	$–	
10.	ddI (Didanosine) 200mg	Tablet	7,951	8,349	696	7,656			7,656	60	128	$–	$–	
11.	ABC (Abacavir) 300mg	Tablet	30,916	32,461	2,706	29,766			29,766	60	497	$1.100	$1.215	
12.	TDF (Tenofovir) 300mg	Tablet	7,951	8,349	696	7,656			7,656	30	256	$–	$–	
13.	NFV (Nelfinavir Mesylate) 250mg	Tablet	444,565	466,793	38,900	427,900			427,900	270	1,585	$0.310	$0.258	
14.	LPV/r (Lopinavir/ Ritonavir) 133.3mg/ 33.3mg	Capsule	38,357	40,275	3,357	36,927			36,927	180	206	$0.900	$0.228	

NATIONAL ART PROGRAM: ARV DRUG REQUIREMENTS FORECAST YEAR 2005 *continued*

No.	Drug Product	*Basic Unit*	QUANTITY TO ORDER							*Issue Pack Size*	COST ESTIMATE			
			Quantity Required	Adusted QR	AMQR	DEOYS	SOH	Quantity on Order	Annual QO		Quantity to Order	COST Generic	COST Branded	TOTAL COST US$
			Total No. Basic Units	*Losses/ Wastage 5%*	*Average Monthly QR*	*AMQR x (11 months) DEOYS*	*Usable Stock on Hand*	*Quantity on Order (No. Units)*	*Quantity to Order (No. Units)*		*Rounded to Pack Size*	*Cost/ Pack Size US$*	*Cost/ Pack Size US$*	
	Drugs Exclusively for Pediatric ART													
15.	NVP (Nevirapine) 10mg/ml oral suspension	240ml Bottle	1,304	1,369	115	1,265			1,265	1	1,265	$–	$17.500	
16.	NVP (Nevirapine) 10mg/ml oral suspension	20ml Bottle								1		$–	$–	
17.	EFV (Efavirenz) 30mg/ml, syrup	??ml Bottle	0	0	0	0			0	1	0	$–	$–	
18.	EFV (Efavirenz), 50mg	Capsule	70,377	73,895	6,158	67,738			67,738	30	2,258	$–	$0.116	
19.	EFV (Efavirenz) 100mg	Capsule	0	0	0	0			0	30	0	$–	$–	
20.	AZT (Zidovudine) 10mg/ml syrup	200ml Bottle	8,045	8,447	704	7,744			7,744	1	7,744	$3.850	$7.100	
21.	AZT (Zidovudine) 100mg capsule	Capsule	0	0	0	0			0	100	0	$0.073	$0.097	
22.	3TC (Lamivudine) 10mg/ml oral suspension	240ml Bottle	5,141	5,398	450	4,950			4,950	1	4,950	$2.000	$6.730	
23.	d4T (Stavudine) 1mg/ml PFR	200mg/ Bottle	2,796	2,935	245	2,695			2,695	1	2,695	$–	$0.048	

NATIONAL ART PROGRAM: ARV DRUG REQUIREMENTS FORECAST YEAR 2005 *continued*

No.	Drug Product	*Basic Unit*	QUANTITY TO ORDER							*Issue Pack Size*	COST ESTIMATE			
			Quantity Required	Adusted QR	AMQR	DEOYS	SOH	Quantity on Order	Annual QO		Quantity to Order	COST Generic	COST Branded	TOTAL COST US$
			Total No. Basic Units	*Losses/ Wastage 5%*	*Average Monthly QR*	*AMQR x (11 months) DEOYS*	*Usable Stock on Hand*	*Quantity on Order (No. Units)*	*Quantity to Order (No. Units)*		*Rounded to Pack Size*	*Cost/ Pack Size US$*	*Cost/ Pack Size US$*	
24.	d4T (Stavudine) 15mg capsule	Capsule	11,839	12,430	1,036	11,396			11,396	60	190	$0.070	$0.071	
25.	d4T (Stavudine) 20mg capsule	Capsule	35,516	37,291	3,108	34,188			34,188	60	570	$0.058	$0.094	
26.	ddI (Didanosine) 10mg/ ml PFR 2g	4oz Bottle	127	133	12	132			132	1	132	$–	$0.737	
27.	ddI (Didanosine) 25mg	Tablet	2,871	3,015	252	2,772			2,772	60	47	$–	$0.053	
28.	ddI (Didanosine) 50mg	Tablet	16,565	17,394	1,450	15,950			15,950	60	266	$–	$–	
29.	ddI (Didanosine) 100mg	Tablet	2,871	3,015	252	2,772			2,772	60	47	$0.100	$0.212	
30.	ABC (Abacavir) 20mg/ml oral solution	240ml Bottle	566	594	50	550			550	1	550	$–	$0.131	
31.	NFV (Nelfinavir) 50mg/g PFR (50mg/1.25 ml scoop)	144g/ Bottle	0	0	0	0			0	1	0	$–	$0.216	
32.	LPV/r (Lopinavir/ Ritonavir) 80mg/20mg/ ml	300ml Bottle	13	13	2	22			22	1	22	$–	$0.139	

Includes all ARV drugs required to meet National ART Guidelines revised November 2004.

All ARV drugs are WHO pre-qualified and registered for use.

Building Blocks for Inventory Management of HIV Tests and ARV Drugs

Inventory Control Systems, LMIS, and Storage and Distribution

December 2005

Contents

Executive Summary

Introduction

A logistics system that manages any health commodity, antiretrovirals (ARVs), HIV tests, or otherwise, must have infrastructure to manage and move commodities, all of which supports the supply chain as a whole. 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 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 takes on even greater importance in the context of managing 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. The discussions and recommendations described below to manage ARVs and HIV tests assume that the basic elements of a performing supply chain are already in place or can be put into place.

When providers do not have consistent supplies of ARVs, due to 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 was among the local STGs or WHO-recommended STGs*:

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

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 the ways in which 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, which can range from six to 24 months
- High price, including a significant jump in price when moving from first-line ART to alternate treatment regimens
- Cool storage needed 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
- 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
- Continued, uninterrupted resupply for patients already on ART
- Special ordering and information requirements for second-line and alternate drug treatment, should these drugs not be 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 recommendations that follow are guiding principles and lessons learned from DELIVER's experience that have proven to be effective in supply chain management of ARVs and HIV tests.

Recommendations: Inventory control system

- Reduce the length of the supply pipeline.
- Use the forced ordering version of the 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.
- Implement a mechanism for returning products for rapid redistribution before expiry.

Recommendations: 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; issues data should not be used as a proxy.

- Refrain from altering the content and formatting of the LMIS to accommodate the funding mechanism.

Recommendations: 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.

Recommendations: LMIS for HIV tests

- In addition to the three essential logistics data items, limit other data collected and reported to data on the total number of tests used by purpose and type of use.
- Use the individual test as the unit for recording.
- Preprint forms with the type of use for each test (e.g., “screening,” “confirmatory,” “tie-breaker”) and write in the brand name by hand. Leave a few blank lines below each type of test to allow for multiple brands of tests used.
- Manage test-related supplies through the existing system for laboratory supplies.

Recommendations: 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.

Introduction

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 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.

Inventory Control Systems

Purpose of an Inventory Control System

An inventory control system informs the storekeeper:

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

The continuous supply of quality ARV drugs and HIV tests can 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 automated 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 System" below for further discussion of this topic.

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

Length of In-Country Commodity Pipeline

The length of the commodity pipeline (determined by adding the maximum stock levels at all levels of the system) is a key consideration in commodity management. This is especially true for ARVs and HIV tests, where a commodity's shelf life is often less than 24 months and can be as little as six months.

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

	Lead Time Stock Level	Safety Stock Level	Review Period/ Order Interval	Min	Max	Emergency Order Point
Level						
Central	3	3	6	6	12	3
Regional	3	2	3	5	8	2
District	2	1	3	3	6	1
SDP	1	1	1	2	3	0.5
Total				**16**	**29**	

[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.

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

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 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 less than 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.

- **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.

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. Once 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 find itself overstocked with ARV drugs at some point. 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 (three-month maximum stock level), if a facility has more than three 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 so that they could 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 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 Record for Returning Drugs 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 handle other issues related to commodity management. These decision must be made using accurate and timely logistics data provided by a logistics management information system (LMIS). Over the long term, data provided through the LMIS can also help to inform policy and product selection decisions.

A logistics management information system 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 uninterrupted supply of commodities and to identify any problems in the supply pipeline. The LMIS is made up of all the forms and documentation used to maintain records and produce reports on the logistics system.

> Do not confuse HMIS with LMIS. HMISs are intended for the collection and reporting of overall program parameters, such as incidence, client load, and performance, and lack the specificity that LMISs provide for managing commodities within the health program. In addition, the time required to collect and process data though an HMIS would mean that it is not available for timely logistics decision making.

An effective LMIS makes information available to decision makers on a regular and timely basis. Information is used to make resupply decisions in the short term and to make procurement and program management decisions in the long term. The need for timely and accurate commodity data increases in the context of 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

There is a close relationship between an LMIS and the inventory control system: the LMIS provides the data required to maintain the inventory control system.

Data collected through the LMIS allow 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 an emergency order needs to be placed. 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

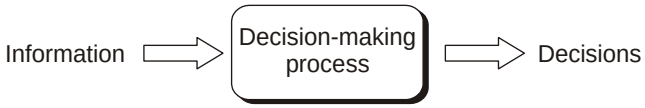
redistribute products to where they are needed. Commodity managers might also use the data to determine exceptionally high levels of product expiry and then initiate action to prevent this situation from happening in the future.

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 overall quality of care of HIV/AIDS clients.

Data for Decision Making

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

Data should only be collected if they will be used for decision making!!!



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

Dispensed to user: data on the quantities of products given to clients/patients for their use (e.g., ARVs) or 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.

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

Stock on hand: data on the usable quantities of stock held at a facility.

Losses and adjustments: data on any quantities of stock that leave the pipeline for reasons other than "dispensed to user"—transfers of stock from one facility to another at the same level.

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 try to collect data that are not immediately relevant for logistics management decision making. An LMIS must collect only those data that will be used for decision making. Data collection forms and reports must be used to collect and transmit that data, but the forms and reports 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, and do we need to order more supplies now?
- Where are our supplies in the pipeline, and 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 discussed 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, are:

- Consumption records: to capture data about the products being used or consumed (dispensing logs or registers).
- Stock-keeping records: to collect information about products in storage (bin cards, stores ledgers).
- Transaction records: to 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 found in an LMIS, 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 or form 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 demonstrated 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 Inventory Control System section above, the amount of data

aggregation will be reduced. This will also reduce the risk of introducing errors into the reporting system and 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 showing the number of drugs dispensed, in which 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, since they 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 many 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 separately and in combination. Furthermore, ARV therapy cannot be interrupted and continued later due to 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 once specific testing protocols have been established for each test purpose, and 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 test results.

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

- Need for simultaneous and uninterrupted 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, include:

- Continued uninterrupted resupply for patients already on antiretroviral therapy (ART)
- Special ordering and information requirements for second-line and alternate drug treatments, should these drugs not be kept routinely at the service site.

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

- 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 that 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, bu, 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 absense 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 clients/patients who access ART services and receive drugs
- Product combinations, regimens, and which products are needed in a complementary manner
- 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
- 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, 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, given the data that are being 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, this decision has always been made with the involvement of policymakers or relevant authorities.

See the illustrative forms, *LMIS Report and Request for Antiretroviral Drugs* and *Report and Order Calculation Form, HIV Test Kits,* in the annex .

2. Avoid overburdening the LMIS by collecting service statistics or other data that do not have direct benefit to managing commodities.

Other data that are not required for logistics purposes may be included on LMIS for HIV tests or ARVs, depending on the particular program's needs, 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 assist 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 of 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.

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 to 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, such as 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 clients, 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.

It is necessary therefore for the LMIS, which generally focuses exclusively on logistics data, also to 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 three-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 following standard formula:

*It is vital to use *average monthly consumption* when determining order quantities once such data are available. This is particularly true in cases where the dispensing protocol may call for giving patients more than a review period of supply. In such cases, month-to-month consumption will vary greatly, and the average consumption must be captured.

Conversely, if you are only using the previous review period dispensed to user, and not an average, then you cannot give more than a review period worth of stock to patients, as doing so would lead to stockouts.

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

In a rapidly expanding program, 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"). Another strategy, considering the patient data, combines logistics data with patient data to determine reorder requirements. In this case, patient-related data, specifically the number of new patients by treatment regimen expected during the next month, are required. Once the 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.

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:

Quantity to Order =
(Consumption* x 3) + (Quantity required for new patients x 3) – Stock on Hand

In a situation where 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:

Quantity to Order =
(Consumption* x 2) + (Quantity required for new patients x 2) – Stock on Hand

Note: In this example, with a two-month "maximum" (1 month of dispensing stock + one month of lead time and safety stock); *lead time must be three weeks or less*.

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 are being used to project reorder quantities, then it is strongly recommended that an automated (computerized) system be used to make those calculations. Further, if an automated system is being used, then it is likely to be used more effectively with a pull system.

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 treatment 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.)

In addition to being a useful tool for monthly ordering, the worksheet can be used for monitoring and supervision. Periodically, program managers can monitor product use with the worksheet 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, etc.), and the program should seriously consider following that practice in the event that bottle quantities change over time or if different suppliers provide the same drug in different quantities. The important point is that the recording unit is consistent, and that it is known and used by all program personnel.

> Zerit is packaged in bottles of 56 tablets, while generic versions of stavudine are packaged in bottles of 60 tablets. All other drugs used in combination with stavudine to make a full regimen (such as efavirenz, lamivudine, and nevirapine) are also packaged in bottles of 60 tablets. A program that only tracks number of bottles would run the risk of patients receiving four fewer tablets per month in a regimen. Similarly, when new patients are started on a nevirapine-based regimen, they only receive half the standard dose to test for toxicity and thus receive 14 or 15 tablets for their first two weeks instead of the full bottle of 30 tablets. Tracking by bottle would make it difficult to account for this dispensing practice.

4. Separate clinical/program information used for program monitoring from logistics and patient data collected for logistics decisions.

As discussed above, 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 as a means of collecting 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 getting 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 fashion. In any case, there is the risk that collected data are not available or used for resupply, 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 to the total number of tests used by purpose and type of use.

HIV tests can have multiple purposes of use: for PMTCT activities, clinical diagnosis, VCT, and blood safety, among others. The LMIS for HIV tests may be used to track quantities of HIV tests used by purpose. Capturing these data has significant benefits for program management, especially for monitoring program expansion and forecasting future needs. One benefit to capturing these data is that program managers can monitor losses and waste of tests by purpose, including waste for acceptable reasons. In some countries, health workers manage separate registers for different types of testing and then aggregate each of these registers to report on a total number of HIV tests dispensed, according to purpose. Another benefit to collecting these data is that the donation or procurement mechanisms for each of these activities may vary, and maintaining use data by purpose can address varying reporting requirements.

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

Logistics data can also be supplemented by a limited amount of patient data. The availability of such data can lend to increased accountability concerning 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, such as the numbers of clients served, is a decision for program managers, while recognizing that the data collected should be limited to avoid making the system cumbersome or unwieldy. Such data should never be collected if they will not be used for decision making.

See the illustrative form, *Daily Log for HIV Tests by Purpose of Use*, in the annex.

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 relatively low volume of HIV tests and be unable to use an entire HIV test kit (which may include 100 tests) before the tests expire. Or a facility stocks out of chase buffer, but still has several tests, so it 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. Preprint forms with the type of test ("screening," "confirmatory," "tie-breaker") and write in the brand name by hand. Leave a few blank lines below each type of test to allow for use of multiple brands of tests.

Because of rapid technology changes in HIV tests, HIV testing programs may use different or more appropriate brands of HIV tests as they become available on the market. Also, for newer and rapidly expanding programs, maintaining continous supplies may be challenging, and often the same brand of test kit that is designated for confirming the results of the initial screening test may be used for screening if the initial test is stocked out. Therefore, it is recommended that preprinted LMIS forms use the designations, "screening," "confirmatory," and "tie-breaker," rather than the brand name of the test, and that some blank lines be left for adding other tests used for each type of testing. The service provider or test administrator can write the brand name of the test next to each test. This may require an extra step in terms of paperwork, but it allows the LMIS to be flexible and adapt to changes in the brand of test being used, without the need to reprint the forms each time a new test is introduced.

In instances where the brands of tests being used do not change frequently over time or the program is able to guarantee a continuous supply, the brand names could be preprinted on the LMIS forms.

See *Report and Order Calculation Form, HIV Test Kits* in the annex.

4. 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 does not have 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.

Storage and Distribution of ARVs and HIV Tests

Purpose of Storage and Distribution

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

Proper storage procedures help ensure that storage facilities issue only high-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, customers can be assured that they have received a high-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 be considered as well. The packaging provides the primary protection to the product during storage and transportation, so 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 this is possible, products should be ordered and issued to the nearest packing unit quantity. For example, if 48 items are required, and 50 is the number of items 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 will 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 generally may 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.

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

While in some cases these special characteristics may require implementation of a unique procedure for handling ARV drugs or HIV tests, 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 storeroom—out of direct sunlight—ARVs should not be opened to repackage them.
- Treat ARVs and HIV tests as you would narcotics and controlled substances: provide a secure storage area with controlled yet continuous access.
- Maintain cool storage (2 to 8 degrees Celsius; 36 to 46 degrees 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 risk expiring before they can be distributed to and used by the client.

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, and
- deliveries to accredited sites only.

Recommendations for Storage and Distribution of ARV Drugs and HIV Tests

1. When feasible, integrate storage and distribution of ARV drugs and HIV test kits.

Integrating the storage and distribution of ARV drugs and HIV tests can help to 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, or 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 stock-keeping and transaction records for each stock movement. Requiring the signature of someone in addition to the storekeeper who is responsible for storing and distributing the product helps protect the 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.

The same level of security the product has in storage should be assured during transport. 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-expire, 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, ensuring that products are used before expiration to reduce waste. In addition, commodity managers must take action immediately if there is a risk that products will expire before they can be used. Action may include returning the products to the supplying facility for redistribution or directly transferring the products to a facility that can use them before they expire and notifying the procurement and program management units.

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

5. Ensure product integrity if reissuing returned drugs.

In an ARV program, some 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. To reduce waste, these drugs can be reissued to other patients. However, these drugs must be inspected before being reissued. 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 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.

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 these 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 may 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.

Annex

Kaamanland HIV/AIDS Program
ARV Drug and HIV Test Supply Chains: A Case Study

This case study describes the supply chains for ARV drugs and HIV tests for the HIV/AIDS program in the imaginary country of Kaamanland and 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 in 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 using 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 determines the number of new patients who will be starting ART the following month and, using the *New ART Patient Worksheet*, calculates the quantity of each drug needed for new patients for the next month. The ART service provider uses the records and worksheet to complete the *LMIS Report and Request for Antiretroviral Drugs*. The report and request are 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 should have 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 document the transfer of drugs using the *Record for Returning 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

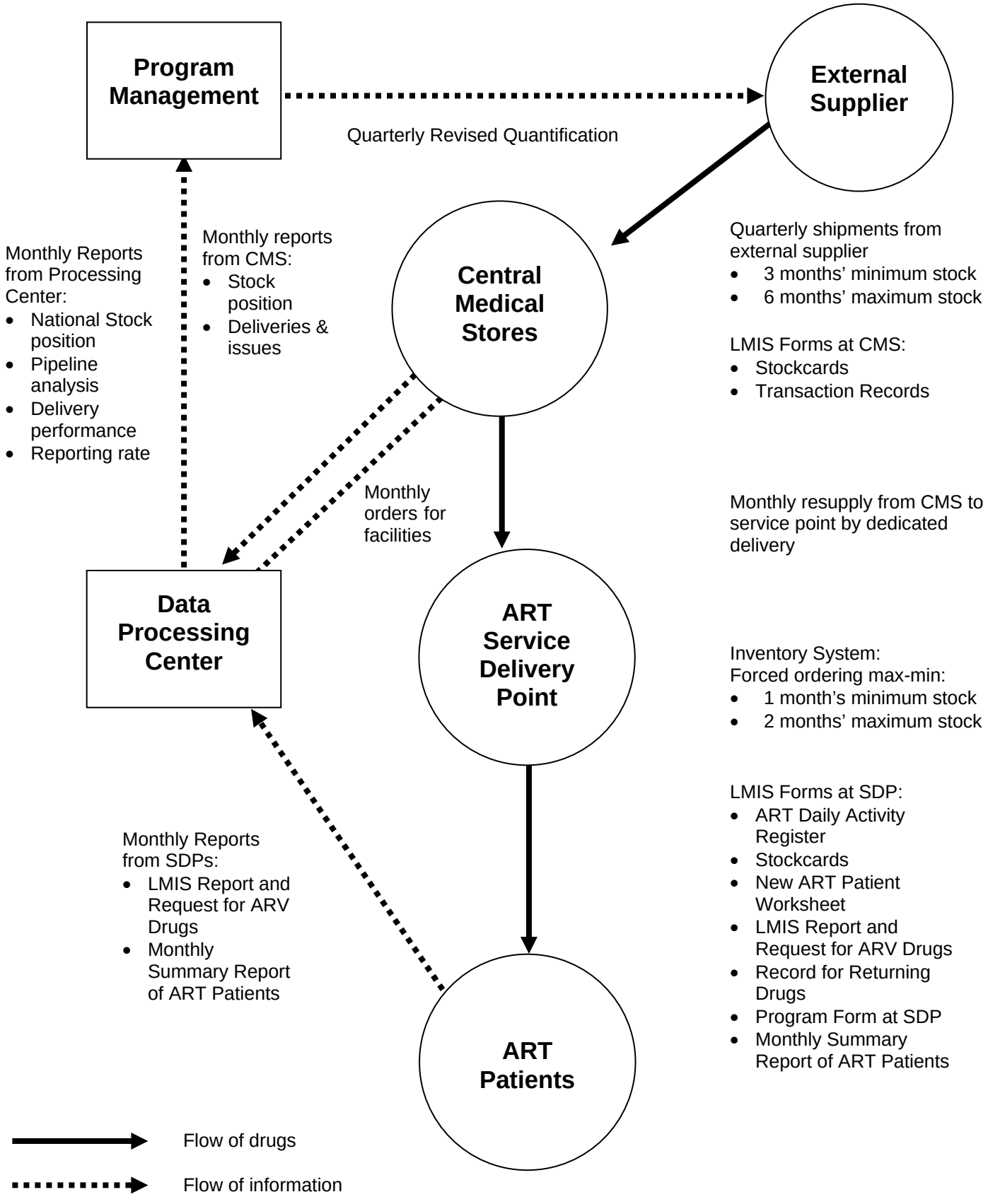
In Kaamanland, HIV testing is conducted in a variety of settings, including voluntary counseling and testing (VCT) centers; clinics offering prevention of mother-to-child transmission (PMTCT); and national, regional, and district hospitals.

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.

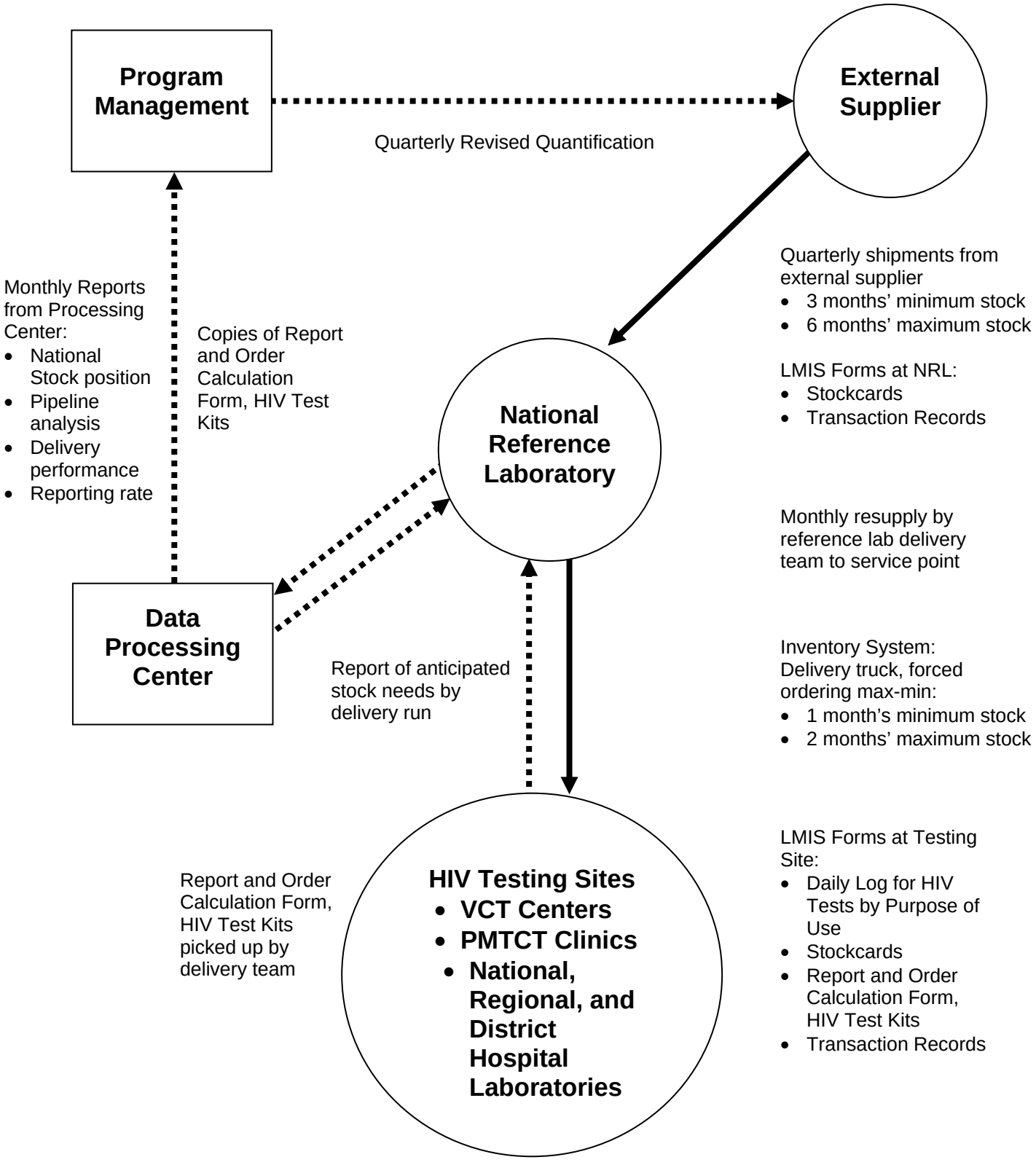
HIV testing sites use the *Daily Log for HIV Tests by Purpose of Use* to record the quantity of each test administered to patients. Stockcards are used to record stocks received and issued, losses and adjustments, and stock on hand for HIV tests stored at the testing site. At the end of each month, the laboratory personnel or providers managing the HIV tests use the records to complete the *Report and Order Calculation Form, HIV Test Kits*. The report and order is then given to the HIV test kit 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 quantification of test kit needs, procurement plans, and shipping schedules with external suppliers.

Kaamanland

ARV Drug Pipeline



Kaamanland
HIV Test Pipeline



Records and Reports for Managing ARV Drugs and HIV Tests

Note: The sample forms included here are for illustrative purposes. While they may be directly applicable in a country program, some modification may 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, preprinting commodity names, units, etc., on forms should be customized to each country or program setting, reflecting the selected standard treatment or testing guidelines.

ART Daily Activity Register: A consumption record used to track ARVs that are issued to clients/patients, to be maintained by the service provider/clinician who dispenses drugs to the patients. The quantities generated would feed into the monthly consumption totals and be used to determine average monthly consumption and reorder quantities.

Worksheet for Calculating Monthly ARV Drug Orders for Estimated New ART Patients: A worksheet for translating estimated numbers of new patients into quantities of products that will be required to treat them.

LMIS Report and Request for Antiretroviral Drugs: A combined logistics report and order form for ARV drugs. Provides a full report of all three essential logistics data and demonstrates the order quantity calculations. The report would be submitted to the supplier and shared with program staff.

Monthly Summary Report of ART Patients: A program report used to report the number of patients on ART by treatment regimen. Provides new patient data for routine ordering in a context of rapid scale-up.

Daily Log for HIV Tests by Purpose of Use: A consumption record used to track use of HIV tests by client/patient, to be maintained by the service provider/clinician who does HIV/AIDS testing. The quantities generated would feed into the monthly consumption totals and be used to determine average monthly consumption and reorder quantities.

Report and Order Calculation Form, HIV Test Kits: A combined logistics report and transaction record for HIV tests. Provides a full report of all three essential logistics data and demonstrates the order quantity calculations. The report and record would be submitted to the supplier and shared with program staff.

Requisition and Issue Voucher: A generic transaction record that includes all basic data to track in the transaction. Some countries include “receipt” information as well on the same form, so that all elements of the transaction are captured on a single record.

Record for Returning Drugs: A transaction record to track products that are returned to the supplier for redistribution. While a generic issue and receipt voucher could also be used, the specific “Record for Returning Drugs” includes information specific to the return that could be important in monitoring the logistics system, service provision, and the overall program as well.

ART Daily Activity Register

		Fixed Dose Combination							Single Dose													
Facility: District: Province:		Stavudine/Lamivudine/Nevirapine Tabs (30/150/200mg)	Stavudine/Lamivudine/Nevirapine Tabs (40/150/200mg)	Stavudine/Lamivudine Tabs (30/150mg)	Stavudine/Lamivudine Tabs (40/150mg)	Lopinavir/Ritonavir (133/33 mg)	Zidovudine/Lamivudine (300/150mg)		Efavirenz Tabs 200mg	Nevirapine Tabs 200mg	Zidovudine Caps100mg	Didanosine Tabs 100mg	Stavudine Tabs 30mg	Stavudine Tabs 40mg	Indinavir Caps 400mg	Nevirapine Syrup	Lamivudine Syrup	Zidovudine Syrup	Lamivudine Tabs 150mg	Didanosine Tabs 50mg		
Date:	Patient Name/Number																					
Total Quantity Dispensed:																					

Worksheet for Calculating Monthly ARV Drugs Orders for Estimated New ART Patients

	Tot. # Pts./Reg.	Formu-lations	# Pts./ Form.	Fixed Dose Combinations (FDC)					Single Drug Formulations (SDF)											
				d4T 30mg 3TC NVP	d4T 40mg 3TC NVP	d4T 30mg 3TC	d4T 40mg 3TC	AZT 300mg 3TC	AZT 300mg	d4T 30mg	d4T 40mg	3TC 150mg	NVP 200mg	EFV 200mg	EFV 600mg	ABC 300mg	ddI 25mg	ddI 100mg	ddI 200mg	LPV/r 133/ 33mg
Adult First Line Regimens																				
d4T 30 + 3TC + NVP <60 kg.	20	FDC	12	12																
		FDC + SDF	6			6							6							
		SDF	2							2		2	2							
d4T 40 + 3TC + NVP >60 kg.	12	FDC	0		0															
		FDC + SDF	10				10						10							
		SDF	2								2	2	2							
d4T 30 + 3TC + EFV <60 kg.	10	FDC + SDF	8			8								0	8					
		SDF	2							2		2		0	2					
d4T 40 + 3TC + EFV >60 kg.	6	FDC + SDF	6				6							0	6					
		SDF	0								0	0		0	0					
AZT + 3TC + NVP	4	FDC + SDF	4					4					4							
		SDF	0						0			0	0							
AZT + 3TC + EFV	4	FDC + SDF	2					2						0	2					
		SDF	2						2			2		0	2					
Adult Second Line Regimens																				
AZT + ddI250 + LPV/r <60 kg.	2	SDF	2						2								2	2		2
AZT + ddI400 + LPV/r >60 kg.	2	SDF	2						2										2	2
ABC + ddI250 + LPV/r <60 kg.	0	SDF	0													0	0	0		0
ABC + ddI400 + LPV/r >60 kg.	0	SDF	0													0			0	0
Total No. Patients per Drug (A)				**12**	**0**	**14**	**16**	**6**	**6**	**4**	**2**	**8**	**24**	**0**	**20**	**0**	**2**	**2**	**2**	**4**
# pills/patient/30 days (B)				60	60	60	60	60	60	60	60	60	60	90	30	60	60	60	60	180
Total Quantity. Drugs by Product for 30 days (= A x B)				**720**	**0**	**840**	**960**	**360**	**360**	**240**	**120**	**480**	**1440**	**0**	**600**	**0**	**120**	**120**	**120**	**720**

LMIS Report And Request For Antiretroviral Drugs

Facility: _____ **Month:** _____ **Max. Stock Level** _____ **Months**

District: _____ **Year:** _____

Region: _____ **Min. Stock Level** _____ **Months**

Product	Basic Unit	Opening Balance	Qty. Rec'd.	Monthly Cons.	Loss/ Adjust.	Closing Balance	New Patient Req's.	Total Expected Cons.	Max. Stock Qty.	Qty. Needed	Qty. to Issue
		A	*B*	*C*	*D*	*E = A+B–C+/-D*	*F*	*G = E+F*	*H = Gx2*	*I = H-G*	*J*
Fixed-Dose Combinations											
d4T30/3TC150/NVP200	tab										
d4T40/3TC150/NVP200	tab										
AZT300/3TC150/EFV600	tab										
Single-Dose Drugs											
AZT 300mg	tab										
d4T 30mg	cap										
d4T 40mg	cap										
3TC 150mg	tab										
ddL 25mg	tab										
ddL 100mg	tab										
ddL 200mg	tab										
EFV 600mg	tab										
LPV/r 133/33mg	cap										
NVP 200mg	tab										

Prepared by: _____

Signature: _____

Date: _____

Remarks and explanation of losses and adjustments:

Monthly Summary Report of ART Patients

Facility: _____ **Month:** _____

District: _____ **Year:** _____

Region: _____

A	ADULT First-Line Regimens	Current No. Patients This Period	Expected No. New Patients Next Period	Total No. of Patients Next Period
A1	AZT 300mg/3TC 150mg + NVP 200mg			
A2	AZT 300mg/3TC 150mg + EFV 600mg			
A3	d4T(30) + 3TC 150mg + NVP 200mg			
A4	d4T(40) + 3TC 150mg + NVP 200mg			
A5	d4T(30) + 3TC 150mg + EFV 600mg			
A6	d4T(40) + 3TC 150mg + EFV 600mg			
B	**ADULT Second-Line Regimens**			
B1	AZT 300mg + TDF 300mg + LPV/r 133.3mg/33.3mg			
B2	TDF/FTC 300mg/200mg+ LPV/r 133.3mg/33.3mg			
C	**PAEDIATRIC First-Line Regimens**			
C1	AZT 10mg/ml + 3TC 10mg/ml + NVP 10mg/ml			
C2	AZT 100mg capsule +3TC 10mg/ml + NVP 10mg/ml			
C3	AZT 100mg capsule +3TC 10mg/ml + EFV 50mg			
C4	d4T 1mg/ml + 3TC 10mg/ml + NVP 10mg/ml			
C5	d4T 15mg + 3TC 10mg/ml + EFV 50mg			
C6	d4T 20mg + 3TC 10mg/ml + EFV 50mg			
D	**PAEDIATRIC Second-Line Regimens**			
D1	ABC 20mg/ml + ddI 10mg/ml (2g)+ NFV 144g PFR			
D2	ABC 20mg/ml + ddI 10mg/ml (2g)+ LPV/r 80mg/20mg/ml			
D3	ABC 300mg + ddI 25mg + NFV 250mg			
D4	ABC 300mg + ddI 50mg + NFV 250mg			
D5	ABC 300mg + ddI 50mg + NFV 250mg			
E	**PMTCT Regimens**			
E1	Mother			
E2	Infant			
	Total:			

Report prepared by:

Name/Signature: _____ Designation: _____

Reviewed by Head of the Institution:

Name/Signature: _____ Designation: _____

Daily Log for HIV Tests by Purpose of Use

X VCT ____ PMTCT ____ Blood Safety ____ Clinical Diagnosis ____ Other ____

For each patient, record the brand of test used for each purpose: screening, confirmatory, or tie-breaker. Write “D” for Determine, “U” for Unigold, and “I” for InstaScreen. At the end of each page/month, record the totals for each brand and purpose and transfer the totals to the Report and Order Calculation Form, HIV Tests.

Date	Patient Name/Number	Screening	Confirmatory	Tie-Breaker	Remarks
03/10/05	000138	D			
04/10/05	000201	D			
04/10/05	000203	D			
06/10/05	000207	D			
09/10/05	000208	D			
14/10/05	000209	D			
15/10/05	000215	D			
19/10/05	000217	U			
20/10/05	000138		U		
23/10/05	000207		U		
24/10/05	000209		U		
28/10/05	000207			I	
					Totals
	Determine	7			7
	Unigold	1	3		4
	InstantScreen			1	1
	Other:				
	Other:				
	Page Total	8	3	1	12
	Monthly Total	8	3	1	12

Report and Order Calculation Form
HIV Test Kits

Facility Name: ***Kaamanland VCT Clinic***
District: ***Wanu***
Health Subdistrict: ***Tunlaw***

Report Period: ***October 2005*** (Month – Year)
Date Report Prepared: ***3 Nov. 2005*** (Day – Month – Year)

HIV Test Kit Description		Basic Unit	Qty. Rec'd	Losses/ Adjustments	Used	Total Used by Type	Maximum Stock Qty.	Ending Bal./ Physical Inv.	Quantity Needed
Type	***Brand***		***A***	***B***	***C***	***D***	***E = D x 4***	***F***	***G = E - F***
Screening	***Determine***	Test	***20***	***0***	***7***	***8***	***32***	***12***	***20***
	Unigold	Test			***1***				
		Test							
Confirmatory	***Unigold***	Test	***10***	***0***	***3***	***3***	***12***	***7***	***5***
		Test							
Tie-Breaker	***InstantScreen***	Test	***0***	***0***	***1***	***1***	***3***	***17***	***0***
		Test							

Summary of HIV Tests by Purpose of Use

	VCT	PMTCT	Clinical Diagnosis	Blood Safety	Other	Totals
Screening	***8***					***8***
Confirmatory	***3***					***3***
Tie-Breaker	***1***					***1***
Totals	***12***					***12***

Remarks and explanations of losses/adjustments:

Prepared by:	***Georgia Brown***	***Georgia Brown***	***Counsellor***	***03/11/05***
	Full Name	Signature	Designation	Date
Reviewed by:	***Helen Highwater***	***Helen Highwater***	**Clinic Director**	***05/11/05***
	Full Name	Signature	Designation	Date

Requisition and Issue Voucher

Requisition and Issue Voucher No.: _____

Ship to: _____

_____

_____

Date: _____

Requisition			**Issue**		**Remarks**
Article	***Quantity on Hand***	***Quantity Requested***	***Shipped***	***Received***	

Requisition:

Requested by: _____ Date: _____

Issue:

Approved by: _____ Date: _____

Shipped by: _____ Date: _____

Receipt:

Received by: _____ Date: _____

Record for Returning Drugs

Sent to: _____

Facility returning drugs: _____

Product Description	Quantity Returned	Expiry Date	Reason for Nonuse

Name of person returning the drugs:_____ Date: _____20___

Signature of person returning the drugs:_____

Driver

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

Name of Driver_____ Date_____20___

Driver'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: _____

_____

USAID
FROM THE AMERICAN PEOPLE

Assessing Supply Chains for HIV/AIDS Commodities

December 2005

DELIVER
No Product? No Program. Logistics for Health

Contents

Abbreviations and Acronyms

ART	antiretroviral therapy
ARV	antiretroviral
ATLAS	Assessment Tool for Laboratory Services
FEFO	first-to-expire, first-out
JSI	John Snow, Inc.
LIAT	Logistics Indicators Assessment Tool
LMIS	logistics management information system
LSAT	Logistics System Assessment Tool
OI	opportunistic infection
PMTCT	prevention of mother-to-child transmission
SCM	supply chain management
SDP	service delivery point
SPARHCS	Strategic Pathway to Reproductive Health Commodity Survey
TB	tuberculosis
VCT	voluntary counseling and testing

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 assessement.
- 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 availablility, 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 procurement, 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.

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, standalone 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

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.

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 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.

Box 2.
Assessing System Performance with the LIAT

In 2002, laboratory services in Uganda were not widely available and often lacked key commodities, while at the same time, the country worked to scale up HIV testing, ART, TB, and other infectious disease services, all requiring laboratory facilities. A health facility survey using an adapted version of DELIVER's LIAT to evaluate SCM of key HIV/AIDS commodities was conducted in June 2002 and looked at the availability of HIV/AIDS prevention, treatment, and care services and commodities.

This survey identified certain supply chain deficiencies that affected the availability and the quality of laboratory services in the country. Many laboratories experienced frequent stockouts of key commodities, and many staff members had not been trained to use the necessary laboratory equipment and materials. The study findings motivated the Ministry of Health and its development partners to act. The U.S. Agency for International Development made additional funding available to DELIVER to provide technical assistance to the Ministry of Health and the national laboratory association for developing an improved supply chain and securing the resources required to ensure a more reliable supply of the necessary commodities to properly run its TB, OI, and HIV/AIDS programs.

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 compo-

nents 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 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 prepack 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 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.

g. 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.

h. 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, and 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

DELIVER 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.

DELIVER 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

Table B1. Primary Indicators by Tool

LSAT	LIAT	PipeLine	LMIS	ATLAS	Stages of Readiness
Organizational context LMIS Product selection Forecasting Procurement of supplies Inventory control Warehousing and storage Transport and distribution Organizational support for the logistics system Product use Finances	LMIS data quality (in "pull" systems) Storage conditions Order fill rate (in pull systems) Stockout frequency Product availability and stock status	Forecast accuracy Existence of an adequate multiyear procurement plan Stakeholder commitment to procurement plan	Stockout frequency Product availability and stock status Rate of consumption Losses and adjustments	Product availability and stock status Availability and condition of equipment LMIS Supervision and personnel Forecasting Procurement Inventory control Warehousing and storage Distribution Organizational support for the logistics system Quality assurance Testing services Finances	Six program domains: • Leadership and program model • Services and clinical care • Management and evaluation • Human resource capacity • Laboratory capacity • Drug management and procurement

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
- 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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