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SUPPLY CHAIN MANAGEMENT OF ANTIRETROVIRAL DRUGS

CONSIDERATIONS FOR INITIATING AND EXPANDING NATIONAL SUPPLY CHAINS

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

Implemented by John Snow, Inc. (JSI) (contract no. HRN-C-00-00-00010-00) and subcontractors (Manoff Group, Program for Appropriate Technology in Health [PATH], and Crown Agents Consultancy, 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
One of the most critical challenges to the global scale-up of antiretroviral therapy (ART) programs is the effective management of a supply chain for antiretroviral drugs. Ensuring an effective supply chain for ART requires international and national policymakers and stakeholders to develop an enabling policy environment that both encourages best practices and protects against activities that waste public resources or that are dangerous to public health. This paper helps define that policy environment from a supply chain perspective; it outlines important policy issues to consider and makes recommendations that are practical and applicable to program managers and policymakers on the ground. The objective of this paper is to guide countries on how to develop a policy to strengthen supply chain management for antiretroviral drugs, so that countries can ensure continuous product availability, maximize resources, and better expand ART programs.

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ABBREVIATIONS AND ACRONYMS

AIDS	acquired immunodeficiency syndrome
ART	antiretroviral therapy
ARV	antiretroviral
DDA	dangerous drug act
FBO	faith-based organization
FDC	fixed-dose combination
FPLM	Family Planning Logistics Management
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
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNFPA	United Nations Population Fund
UNICEF	United Nations International Children's Emergency Fund
USAID	United States Agency for International Development
WHO	World Health Organization

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

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PREFACE

This paper identifies and discusses some key supply chain management considerations to address and plan for as 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 review the implementation of supply chain systems as new lessons are learned and will be updated as programs evolve and new evidence emerges. Thus, comments, feedback, and experiences are welcomed and encouraged.

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.

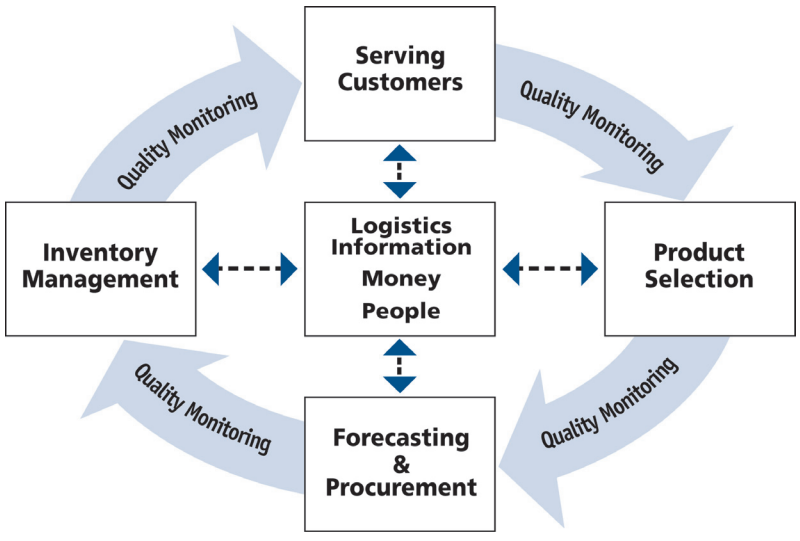
INTRODUCTION

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, 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:

Figure 1. Logistics Cycle



- a limited number of commodities with few changes in technology or formulation over time
- a commitment to maintaining a full supply of selected products
- a program of sustained and consistent financial and technical support for systems development and maintenance
- either the use of external procurement mechanisms, which are usually selected and paid for by donors, or the extensive use of donated products
- a group of dedicated program personnel whose responsibilities include supply chain management.

Recent health-sector reform strategies are designed to eliminate the large number of vertical systems in favor of an efficient, integrated structure that is capable of handling all essential health commodities. Although integrated supply systems are technically feasible, implementation in many countries has been fraught with practical difficulties (Bates et al. 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 these expensive, highly potent, life-saving medications. Although this level of concern has declined, real fears remain. Policymakers and program managers have realized that implementation of effective supply chain strategies can play an important role in minimizing some negative outcomes, including the following:

- risk of emerging widespread drug resistance among patients as the result of supply interruptions or procurement of poor-quality drugs
- leakage of ARV drugs from the public sector into the private sector or to other countries, thus disrupting pricing patterns, affecting forecasting and donor support, and increasing the likelihood of drug resistance among patients if the drugs are prescribed or used improperly
- increased expense to programs that already lack sufficient funds for buying and delivering drugs for essential health problems.

CHANGING PRIORITIES IN THE CONTEXT OF A BURGEONING HIV/AIDS PANDEMIC

A combination of factors—including prolonged activism for people living with HIV/AIDS (PLWHA), 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 Plan for AIDS Relief released funds geared at scaling up antiretroviral treatment in particular. The World Health Organization (WHO 2003b) 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 road map 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 programs 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 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 currently being filled by the private sector may switch to the public sector. A scenario that has already been observed in a number of countries is that a significant number of patients already receiving drugs through the private sector will switch to free-of-charge or highly subsidized drugs in the public sector, resulting in an influx of ART-experienced individuals. If the initial supply of drugs is quantified for ART-naïve patients (first-time ARV drug users), such a switch could result in a greater than anticipated need for second-line drugs if the ART-experienced individuals who paid for their treatment in the past were nonadherent or were treated with suboptimal or inconsistent regimens. This category of patients could have higher failure rates than those without prior ARV exposure, which would affect existing forecasts, procurement plans, and overall program costs because second-line drugs tend to be more expensive.

Developing and standardizing a range of eligibility criteria that address these and other related issues is challenging, given the lack of data available to guide policymakers in predicting the effect of specific decisions at this time. Nonetheless, clear operational guidance for service providers and implementers should be developed and adapted over time and as programs evolve.

Key Consideration 3: Standardizing prescribing and dispensing practices for ARV drugs is critical for supply chain planning and for promoting patient adherence and rational drug use.

Before the release of funds for expanding the public-sector ART programs, much of the ART service provision in resource-poor countries occurred through private for-profit companies, employer-based schemes, nongovernmental organizations (NGOs), or faith-based outlets. In most cases, patients had to pay for ARV treatment regimens. As national public-sector programs continue to scale up services, standardized operational guidelines for prescribing and dispensing practices—especially as they relate to affordability—must be carefully crafted. The need for thorough and comprehensive guidelines is not a new consideration and is recognized as a key factor in enhancing rational drug use of essential medicines (box 1). But, one finds a number of important supply chain implications when developing prescribing and dispensing guidelines. In many countries, because the ARV drugs are provided in full supply for only a limited number of patients, prescribing and dispensing guidelines can play an important role in ensuring that the drugs are maintained at recommended inventory levels and that shortages, stockouts, and overenrollment of patients are avoided. Also, the guidelines can play a critical part in helping to reduce the risk of intermittent treatment caused by a fragmented drug supply. Evidence from ART service provision in the private sector in Kenya and Uganda demonstrates that when an element of cost recovery or cost sharing exists for ARV drugs, the attendance of patients at clinics to collect their medications fluctuates every month according to their purchasing power.

Thus, it is important to ensure that prescribing and dispensing guidelines address all those issues. At the very least, the guidelines should recommend measures to ensure that regimens are prescribed according to national standard treatment guidelines and that three ARV drugs are always prescribed together and in the correct combination and dosage. Using preprinted prescriptions is one approach 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

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 one is consistent with recommendations from the STGs. Similarly, only three of the 12 prescribed pediatric regimens are consistent in STG recommendations.

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 for supply chain management.

Key Consideration 4: ARV drug supplies should be closely linked to the ART service capacity at both the national and facility levels.

Many countries in the process of scale-up have used the quantity of available funding for drug procurement as one way of setting targets for expansion. Although obviously the quantity of the national drug supply is a key factor in determining how quickly programs can expand, another critical factor that is sometimes downplayed is the capacity of the program or of the health facilities and providers to deliver uninterrupted, safe, and effective care and treatment to the patient, as demonstrated in the example above. Underestimating service capacity and the potential effect of such programmatic, clinical, and financial factors on supply chain management can lead to myriad problems. As an example, overprocuring ARV drugs to meet national targets without taking into account the service's or facility's capacity can result in large overstocks of drugs that eventually expire or that leak out of the system, which could lead to withdrawal of funding for ARV drug purchases from donors. This problem is especially true for costly second-line regimens.

Key Consideration 5: To ensure uninterrupted, safe, and effective ART service provision, the programs should establish minimum requirements for facilities and should conduct ART site selection and accreditation on the basis of those requirements.

As a first step toward evaluating service capacity, policymakers must define minimum standards or requirements for providing uninterrupted, safe, and effective ART service. Those requirements can range from very simple conditions (including the presence of trained nurses, clinical guidelines, a secure box for dangerous drugs, 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

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.

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 et al. 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* (2003a), 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 a drug-resistant virus. As a first step, national committees involved in updating national essential medicines lists (NEMLs) and for developing standard treatment guidelines (STGs) should consult WHO's recommendations when selecting ARV treatment regimens that are appropriate for their particular country setting.

Key Consideration 6: Selection of ARV drugs, regimens, formulations, and packaging will affect procurement, forecasting, and distribution, and those relevant supply chain issues should be considered in the process of selecting ARV drugs.

STGs for ART should provide clear criteria for first- and second-line regimens, for the management of patients experiencing toxicity or failing treatment, and for the treatment of specific subgroups, such as patients with tuberculosis, pregnant women, children, and health workers who require post-exposure prophylaxis. Considerations should include clinical and operational factors such as efficacy, availability, pill burden, toxicities, drug interactions, teratogenicity (such as with efavirenz), and cost. As an example, high pill burdens can often lead to poor adherence; thus, use of fixed-dose combinations (FDCs), where possible, should be clearly specified. First- and second-line ARV regimen choices, as well as formulation (FDCs versus single pills) and packaging decisions, will affect procurement, forecasting, and distribution and should be carefully reviewed and evaluated as the medications are implemented. Programs should develop clear guidelines for making STGs operational at service delivery levels. Service providers and supply chain managers should sit on product selection committees to enhance the way in which they operate both the STGs and the design of ART programs.

Key Consideration 7: ART program managers and product selection committees may need frequent updates to review ARV drugs on national essential medicines lists and to be in line with growing evidence and experience as treatment is expanded in multiple resource-poor countries.

Adding ARV drugs to NEMLs will greatly facilitate the implementation and enforcement of STGs and the ability of programs to monitor rational drug use and to effectively manage the supply chain for the drugs. In most countries, NEML revisions occur about every five years. In countries that do not already have ARV drugs on their NEML, an addendum specific to ARV drugs should be considered if a full review or revision is not possible. Given rapid changes in ARV drug technology and falling prices, five-year revisions may be too slow to keep pace with changing recommendations for ART. Clinical care committees may need to review and update the ARV drug portion of NEMLs on a more frequent basis—and in line with the growing body of experience coming from countries—as the committees expand treatment in resource-limited settings.

Key Consideration 8: Policymakers 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 (PLWHA). 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 information 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 intermittent provision of treatment, implementation of an LMIS is considered a critical intervention when establishing ART programs. Although it is too early to know the costs of developing such systems, the issue of allocating financial resources for development and maintenance must be addressed. Without funding for this purpose, ARV drugs of the right type and in the right quantity will likely not reach the ART care sites and, ultimately, the people living with HIV/AIDS (PLWHA) on a regular and timely basis.

Ideally, the LMIS should be designed and be in place before the distribution of ARV drugs begins. Practically, this arrangement may not be feasible, especially given the focus on rapidly scaling up access to treatment. But development of an LMIS that is specifically for ARV drug tracking should be a priority intervention during the early stages of ART program implementation. In the short-term, the LMIS may need to begin as a parallel system;

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 LMISs for ARV drugs. The LMISs 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.

however, the cost-effectiveness of such an approach should be continually reassessed in the medium to long term, as more PLWHA receive treatment and as health system requirements and capacity change over time (box 4).

In addition to an LMIS, functioning systems for individual patient's medical record keeping, reporting, and monitoring are critical for providing routine feedback from clinical and pharmacy records. This set of systems allows toxicity, resistance, dropouts, and stock status to be detected and reported regularly; it allows the forecast of needs to be adjusted and for the shipment quantities and product formulations to be changed as needed. Similarly, given highly mobile populations in many resource-limited settings, the ability to track ARV supply needs as patients move through the system is critical to maintaining as many patients on uninterrupted treatment as possible. Such a system must take into consideration issues of patient confidentiality so that inadvertent disclosure is not made.

When designing a 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 crosscheck 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 (HMISs) (for service use data) and LMISs (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 crosscheck data from an LMIS with that from an 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 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 toward ensuring the use of logistics data and lead times to make resupply decisions and thus to prevent stockouts.

Key Consideration 14: In new programs, program managers should consider a different inventory control mechanism for second-line ARV drugs as a way to reduce drug costs and opportunities for the mismanagement of ARV drugs.

ARV drugs used in first-line regimens are generally significantly less costly than those required for alternate or second-line regimens. Because many of the first-line regimens are available in generic fixed-dose-combination formulations, those pills cost significantly less than second-line drugs and are easier to manage throughout the in-country supply chain. Particularly in the first few years that programs scale up, the drug requirements for first-line drugs will far exceed the quantities of drugs required for second-line regimens. Furthermore, site requirements for quantities of second-line regimens will be much more difficult to predict. Assuming that a population made up primarily of ART-naive users is receiving treatment through the public sector, the majority of patients will be on first-line drugs, and second-line regimens will not be required in large quantities during the first and second years. Substitution drugs for first-line treatment are intended for those patients who develop toxicity or side effects either for recommended first-line treatment or in the case of drug interactions. Although those drugs are slightly more costly and are not required in large quantities, a stock of the substitutions must be maintained at sites, because they will be required immediately to ensure that patients can substitute one drug and continue on ART rather than stopping all treatment unnecessarily. For second-line regimens, however, patients can wait a few weeks or months before they switch regimens, thereby allowing for some flexibility in regard to where drugs are stored.

To reduce the holding cost of second-line drugs and also to reduce the opportunities for pilferage or mismanagement of ARV drugs, supply chain managers should consider selecting a different inventory control mechanism for second-line regimens, compared to what may be used for first-line drugs (box 5).

Another mechanism is for the program to contract emergency distribution using courier services, which guarantee rapid distribution of ARV drugs from central storehouses to distribution points or facilities. Although those services are likely to be costly, such contracts will ensure timely and consistent deliveries and are still likely to cost less than maintaining higher buffer stocks of the drugs for alternative regimens at each site. Also, maintaining a central stock of the items will also 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

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.

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 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 management system 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 2004a).

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 Plan for AIDS Relief.

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 International Children's Emergency Fund (UNICEF), and Global Drug 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 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 ARV 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 national level will be responsible for coordinating the funding and procurement of ARV drugs. The mandate of the organization will be to coordinate and advocate for specific financial and procurement resources to meet the identified requirements from the forecast, as well as changing needs as the program evolves. As an example, there are often multiple recipients for ARV drug funding in a given country.

The World Bank's Multicountry AIDS Program will often work outside the Ministry of Health with the multisectoral national AIDS commission, which is located in the president or prime minister's office. The Global Fund to Fight AIDS, Tuberculosis, and Malaria often identifies the Ministry of Finance as its principal recipient. U.S. government funds or financing from other bilateral agencies will often be channeled through the Ministry of Health. Without a body to oversee; to coordinate; and to track amounts of money promised, time periods of commitment, and actual release of funds, then identifying gaps in funding will not be easy or systematic. Furthermore, advocating for more resources and conducting procurement planning to ensure an uninterrupted supply

at the national level will be even more challenging. Ultimately, the lack of coordination is likely to lead to supply imbalances, stockouts, and wasted resources.

In the long run, tracking the various inputs will also allow the national program to plan for funding of ARV drugs past the first two or three years for which it has funding commitments. To date, few funding organizations have committed funds for any national program during the past three years. Tracking incoming funds for drug and other commodity purchases, such as for HIV/AIDS and ART programs scale-up, will facilitate planning for procurement and resource mobilization in the case of funding shortfalls.

Key Consideration 27: Policymakers and program managers should involve politicians and communities early in planning the ART program to promote ownership, to share responsibility for access decisions with people living with HIV/AIDS, and to manage expectations around national goals.

Involving people living with HIV/AIDS (PLWHA), other community members, and the politicians in the decision-making process, and developing communication strategies to target those groups, will be critical to the success of an ART program. In countries most affected by the HIV/AIDS pandemic, politicians are under increasing pressure to demonstrate their commitment to addressing HIV/AIDS as a national issue. Involving politicians during early policy development can be useful in addressing issues of stigma and discrimination, which can be a significant barrier to ART uptake and ultimately can affect the status of ARV drugs in the supply chain. Poor uptake could result in overstocks and wastage. Furthermore, if politicians participate in and are educated and informed about the national strategy and components in the operational plan, there is less likelihood that they will enact ad hoc policies under pressure. Instead, they will respond in ways that are consistent with existing policies and decisions.

Communities play a critical role in a successful ART program across the nation. Because the incoming supply of ARV drugs will still not be sufficient to treat all clinically eligible PLWHAs, the community can be involved in developing social criteria at the local level for ART eligibility and enrollment. This involvement is likely to assist in managing expectations and in reducing resentment between the haves and have nots and the community and service providers at facilities. Community involvement can also be critical in promoting adherence, in educating patients in the proper use of drugs, and in ensuring that facilities are transparent and accountable for implementing quality ART services. The most effective solutions for many issues with which programs are still grappling may, in fact, come from the community.

Key Consideration 28: When defining access criteria and referral mechanisms for ART, policymakers and program managers should consider implications for supply chain management and patient tracking.

In many countries, how patients will receive drugs when they move from one region to another is a significant challenge that ART programs have not yet addressed. Programs will need to define the mechanism by which patients may be able to change their resupply or dispensing point when relocating within the country. This mechanism is especially important if the supply of ARV drugs is rationed by geographic region, with each site or region receiving an allocated cap on 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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