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GUIDE FOR QUANTIFYING ARV DRUGS

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GUIDE FOR QUANTIFYING ARV DRUGS

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Abstract
Successful implementation and expansion of antiretroviral therapy (ART) services depend on the continuous availability of high-quality antiretroviral (ARV) drugs and on the supply of a wide range of HIV/AIDS-related commodities. The nature of ART and the specific characteristics of ARV drugs and how they are used pose particular challenges for managing the supply chain for ARV drugs. Although some general considerations for managing the supply chain for ARV drugs are discussed in this guide, the primary focus and purpose of the guide are to describe the process and the methodologies used for quantifying ARV drug needs. Quantification of health commodities is a process that includes estimating the quantities and the cost of products required to meet customer demand and to fill the pipeline with adequate stock levels, taking into account service delivery capacity, supply pipeline requirements, and resources available for procurement.

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ACRONYMS

3TC	lamivudine
ABC	abacavir
ABC	A, B, C categories (analysis for classification)
AIDS	acquired immunodeficiency syndrome
AMQR	average monthly quantity required
ANC	antenatal care
ART	antiretroviral therapy
ARV	antiretroviral
AZT	zidovudine
ddI	didanosine
d4T	stavudine
EFV	efavirenz
FDA	Food and Drug Administration (U.S.)
FPLM	Family Planning Logistics Management
FTC	emtricitabine
HAART	highly active antiretroviral therapy
HIV	human immunodeficiency virus
IDV	indinavir
LMIS	logistics management information system
LPV/r	lopinavir + ritonavir
MSH	Management Sciences for Health
NFV	nelfinavir
NGO	nongovernmental organization
NVP	nevirapine
OI	opportunistic infection
PEP	post-exposure prophylaxis
PEPFAR	President's Emergency Plan for AIDS Relief
PMTCT	prevention of mother-to-child transmission
SQV	saquinavir
STG	standard treatment guideline
STI	sexually transmitted infection
TB	tuberculosis
TDF	tenofovir
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNFPA	United Nations Population Fund
UNICEF	United Nation's International Children's Emergency Fund

USAID	United States Agency for International Development
USG	United States Government
VCT	voluntary counseling and testing
VEN	vital, essential, nonessential
WHO	World Health Organization
ZDV	zidovudine

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PREFACE

A major challenge to initiation and expansion of antiretroviral therapy (ART) services in resource-poor countries that have been most affected by the HIV/AIDS epidemic has been the limited capacity of health commodity supply chains to ensure a reliable supply of the products at service delivery sites to support HIV prevention, care, and treatment programs. Successful provision of ART services depends not only on the continuous availability of high-quality antiretroviral (ARV) drugs but also on the supply of a range of HIV/AIDS-related commodities.

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

The nature of ART and the specific characteristics of ARV drugs and how they are used pose particular challenges for managing the supply chain for ARV drugs. Although some general considerations for managing the supply chain for ARV drugs are discussed in this guide, the primary focus and purpose of the guide are to describe the process and the methodologies used for quantifying ARV drug needs. Further technical aspects of managing the supply chain for ARV drugs are discussed in depth in other sections of the DELIVER *Guidelines for Managing the HIV/AIDS Supply Chain* (John Snow, Inc., 2005a).

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

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

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

INTRODUCTION TO QUANTIFICATION

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

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

DEFINITION OF TERMS

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

CUSTOMER

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

CUSTOMER DEMAND

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

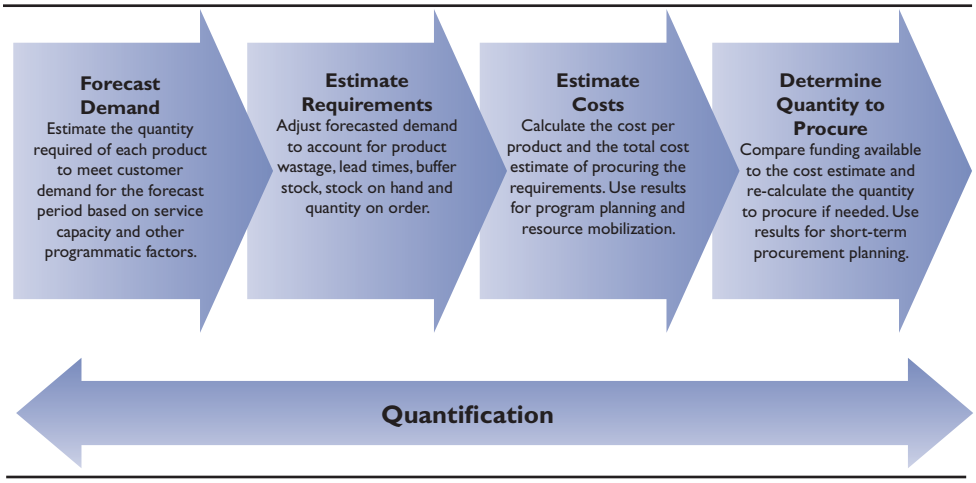
PRODUCT WASTAGE

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

STEPS IN QUANTIFICATION

Figure 1 represents the steps in the quantification process.

Figure 1. Steps in Quantification



FORECASTING DEMAND

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

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

ESTIMATING COSTS

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

DETERMINING THE QUANTITY TO PROCURE

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

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

FORECASTING METHODOLOGIES

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

- demographic data based on characteristics of the target population (e.g., age, sex, geographic location, and urban or rural location)
- morbidity data on prevalence or incidence of disease or infection in the target population
- service statistics data on the number of service delivery sites, the volume of services or number of patients per site, and the type of service received
- logistics data on consumption, losses, and adjustments to inventory, and the stock on hand at the various levels of the in-country supply chain.

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

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

THE CONSUMPTION-BASED METHODOLOGY

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

THE ADJUSTED CONSUMPTION METHODOLOGY

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

THE MORBIDITY-BASED METHODOLOGY

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

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

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

THE IMPORTANCE OF STANDARDIZATION IN QUANTIFICATION

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

- The number of experienced service providers is small relative to the number of treatment sites, and STGs are an essential tool for helping new service providers deliver quality care for patients.
- ART service provision consists of providing three or more different ARV drugs in deliberate combinations and doses. Even a slight deviation from predefined combinations can have a negative impact on the health of the patient by reducing the efficacy of a given product or by resulting in adverse side effects.
- In resource-limited environments a public health approach is used to develop the criteria for product selection and STG development, meaning that the choice of drug combinations not only are based on safety and efficacy criteria but also include cost considerations. Cost considerations are included so that programs are able to treat as many patients as possible with available funding. Without STGs, physicians may choose unaffordable ARV drug alternatives, which will increase costs for programs and individuals and which could ultimately compromise product availability.

Standardization of treatment guidelines is especially critical in the context of quantification. In the absence of quality logistics data, quantification will likely be conducted using the morbidity-based methodology. Standard treatment guidelines must exist and must be clearly documented and disseminated to enhance the accuracy of the quantification using this method. Because ARV drugs are provided in varying combinations to treat patients, quantification is virtually impossible without the existence of STGs. DELIVER has worked in several countries where STGs for ART have been incomplete or have been inconsistent at the time of the quantification, thereby delaying quantification and procurement until the STGs could be finalized.

BACKGROUND

Successful ART depends on lifelong patient adherence to prescribed ARV drug regimens and on maintenance of a full supply of ARV drugs at ART sites. The threat of drug resistance and changes in patients' responses to treatment over time make it imperative to ensure a reliable, flexible, and uninterrupted supply of quality ARV drugs that respond to patient needs and that are available when and where patients need them at an acceptable cost. One must understand the specific characteristics of ARV drugs, the ways in which they are used, and the special requirements for storing and handling them to achieve those goals. This knowledge must be incorporated into the quantification of needs to ensure procurement of the right quantities of the right drugs.

CHARACTERISTICS OF ARV DRUGS

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

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

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

Different doses of some ARV drugs are available to enable adjustment of treatment regimens to individual patient needs—for example, stavudine (20 mg, 30 mg, or 40 mg) and didanosine (25 mg, 100 mg, or 200 mg). Single-drug formulations must be available for substitution within first- and second-line regimens because some patients develop side effects or toxicity to individual drugs, and because three completely different ARV drugs for second-line regimens must be available for patients who develop resistance to first-line

drugs. Specific formulations for pediatric treatment regimens include oral suspensions (syrups) and children's dosages, which are adjusted for weight and body surface area measurements. In addition, quantifications will need to be updated to accommodate procurement of new ARV drug formulations and more user-friendly fixed-dose combinations as they become available on the market.

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

TABLE 1. EXAMPLES OF SINGLE DRUG FORMULATIONS (ILLUSTRATIVE LIST ONLY)

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

a. Lopinavir exists in co-formulation with ritonavir (LPV/r = Kaletra®) as a boosted protease inhibitor.

b. Ritonavir is a protease inhibitor that can be used alone or in combination with other protease inhibitors (lopinavir, indinavir, or saquinavir) to increase their potency, thereby allowing lower doses to be used. Lower doses can reduce the frequency and severity of side effects.

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

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

More information on suppliers, packaging, storage, shelf life, and pricing of those and other ARV drugs is available from *Logistics Fact Sheets: ARV Drugs* (DELIVER 2006a). The World Health Organization's publication, *Scaling Up Antiretroviral Therapy in Resource-Limited Settings: Treatment Guidelines for a Public Health Approach* (WHO 2003a) has additional information on adult and pediatric dosing regimens and on prescribing guidelines. Those lists are not intended to be exhaustive, and readers should refer to in-country standard treatment guidelines and to other sources for up-to-date information on which drugs are available and approved for use in particular countries.

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

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

TYPES OF ART AND COMMON ARV DRUG REGIMENS

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

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

TABLE 3. EXAMPLES OF COMMON ARV DRUG REGIMENS (ILLUSTRATIVE LIST ONLY)

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

CHALLENGES SPECIFIC TO FORECASTING DEMAND FOR ARV DRUGS

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

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

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

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

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

The accuracy of forecasts will rely heavily on the completeness and reliability of data and on the level of adherence to STGs. To enhance the likelihood of accurate quantifications using the morbidity-based methodology, STGs should be clearly documented and disseminated, and all service providers should be adequately trained in ART.

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

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

- availability and continuity of funding for procurement of ARV drugs
- application of standard treatment guidelines by prescribers at all ART sites
- continued availability of ARV drugs at ART sites so that patients requiring a change in regimen will be able to substitute or switch, when needed
- service delivery capacity, patient access to treatment and uptake, patient adherence, and follow up
- length of time before patients will experience side effects, toxicity, treatment failure, and drug resistance to ARV drugs
- patient weight before treatment and length of time on ART before weight gain
- procurement and supplier lead times and shipment schedules
- consumption and stock levels of ARV drugs
- supplier production capacity to meet demand.

STEPS IN THE QUANTIFICATION

The following approach to quantification is based on the experience of DELIVER advisors in conducting ARV drug quantifications in eight countries. The challenges and lessons learned from this experience have been incorporated into the step-by-step approach to quantification presented here. Examples from Excel spreadsheets are used to illustrate the steps in developing a quantification for a national ART program.

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

PREREQUISITES TO QUANTIFICATION

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

DEFINE THE SCOPE AND PURPOSE OF THE QUANTIFICATION

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

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

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

- quantifications by funding source (government or donor organizations that fund procurement of commodities may require separate quantifications)
- quantifications by supply chain (quantification for products that may be managed through separate funding, procurement, and distribution systems, for example, through a network of rural-based, church organizations).

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

- Is the quantification to inform donors about funding requirements and to advocate for resource mobilization for ARV drug procurement?
- Is the quantification to estimate ARV drug needs and to assess the stock status of the in-country supply pipeline so that supply imbalances can be identified and corrected?
- Is the quantification to support an estimate of commodity procurement, storage, and distribution costs?

The quantification exercise should answer the following key questions:

- How many patients can be treated with available funds? For how long can they be treated? Or, conversely, how much would it cost to treat a target number of patients within a given time period?
- How long will current stocks last given current consumption and expected rates of growth?
- What quantities of ARV drugs need to be procured, and when are the quantities needed to avoid stockouts and to support program expansion?

DESCRIBE THE PROGRAM

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

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

DETERMINE THE PERIOD OF THE FORECAST

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

are recommended, and such plans should be revised and updated every three to six months to reflect actual services provided and quantities of commodities used.

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

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

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

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

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

COLLECT THE REQUIRED DATA

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

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

Step 1. Identify the type of program (e.g., Ministry of Health, nongovermental organization, mission or religious, or pilot or research).

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

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

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

- adult and pediatric first-line treatment regimens with single-drug substitutes for side effects, toxicity, pregnancy, and HIV/TB co-infected patients

- adult and pediatric second-line treatment regimens for patients who develop treatment failure or viral resistance
- PMTCT (short-course therapy and single-dose nevirapine regimens for both mothers and newborns)
- treatment regimens for patients with HIV/TB co-infection
- PEP (regimens for prophylaxis of high-risk exposure and low-risk exposure).

Step 5. Verify that all ARV drugs required in the STGs are on the national essential medicines list and are currently registered for importation and use in the country. Include all presentations of each ARV drug as follows:

- form and strength (tablet, capsule, oral suspension, and all dosages available)
- single-drug formulations and fixed-dose combination drugs
- pediatric formulations.

Step 6. Identify suppliers for each ARV drug formulation.

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

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

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

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

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

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

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

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

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

Step 1. Obtain national- and facility-level logistics data on ARV drug consumption, losses and adjustments, and stock on hand, if available.

Step 2. Calculate the expected wastage rate of ARV drug products because of loss or damage through normal handling or nonuse, that is, ARV drugs returned by patients that cannot be dispensed to another patient. In the absence of actual data, this expected wastage rate is currently assumed to be five percent until data from stock cards become available.

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

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

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

Step 6. Confirm facility order intervals.

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

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

- total number of existing patients (adult and pediatric) and the number of patients on each treatment regimen
- estimated number of new patients who will initiate ART within each forecast year on a standard first-line regimen
- phasing-in rate, or program expansion rate—the percentage of the total number of new patients who will have initiated ART by the end of each month or each quarter of the forecast year
- of the number of patients on first-line regimen (adults and children), the estimated percentages of patients who will experience side effects or toxicity to one of the three drugs or will become pregnant and need to switch to a single-drug substitute within the first-line regimen (for example, severe anemia to ZDV, side effects to d4T, teratogenicity to EFV, or severe rash to NVP)[1]
- estimated percentage of patients who will experience treatment failure or will develop resistance to one or more of the three drugs in first-line regimen and will require a complete regimen change to second-line regimen
- estimated percentage of patients on second-line regimen who will experience side effects or toxicity to one of the three drugs and who will need to switch to a single-drug substitute within the second-line regimen[1]
- estimated percentage of patients within each treatment regimen who will receive different doses of ARV drugs according to body weight (for example, d4T 30 mg if patient weight is less than 60 kg or d4T 40 mg if patient weight is more than 60 kg) and surface area (body weight and surface area measurements are needed to determine pediatric dosages)
- estimated percentage of patients who are expected to be on concurrent TB and ART treatment who will require a change in ARV drug regimen

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

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

PREPARE FORECAST DEMAND

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

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

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

ADJUST THE FORECASTED DEMAND

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

An assessment of service delivery capacity will help determine (a) the greatest number of patients who can realistically initiate and continue treatment and (b) the appropriate quantities of product that can be used correctly to meet demand. Although service delivery capacity could actually exceed supply—in which case the quantities of ARV drugs required could be increased to treat more patients, given available funding—more commonly, the constraints in service delivery capacity can significantly reduce the number of patients who can be treated with quality ART services and, therefore, the quantities of ARV drugs that would be required. Any

changes in the forecasted demand because of capacity constraints should be agreed on through consultation and consensus with key stakeholders. At this point, the next step is to estimate the quantities of ARV drugs to order.

ESTIMATE REQUIREMENTS

At this step in the quantification,[2] an assessment is needed of the supply status within the country to calculate the total quantity required of each ARV drug. The requirements estimate should be the amount that can reasonably be expected to be stored, distributed, and used before expiration. It should include the quantities of ARV drugs required to meet the forecasted demand and to fill the pipeline to ensure continuous supply at ART sites.

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

The steps for estimating requirements consist of the following:

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

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

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

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

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

2 This step and step 4 in the next section can be completed by using Excel spreadsheets, as described, or using DELIVER PipeLine software for procurement planning to determine quantities to order and the shipment delivery schedule. Visit the DELIVER website, http://www.deliver.jsi.com, to obtain the PipeLine software and the user's manual.

Step 6. From this new quantity, subtract the total stock on hand of each ARV drug in the system on the last day of the month before the quantification was conducted. In the absence of reliable or complete data from all levels of the in-country supply chain, you may need to make assumptions about current stock levels. At the very least, you should deduct quantities of stock on hand at the central warehouse and at all intermediate warehouses and storage points.

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

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

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

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

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

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

ESTIMATE COSTS

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

The steps for calculating the cost of the requirements are as follows:

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

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

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

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

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

See appendix A for an example of an Excel spreadsheet that was used to complete these calculations.

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

DETERMINE QUANTITY TO PROCURE

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

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

Second, in situations where the cost estimate for procurement exceeds the available funding, an adjustment has to be made to the requirements estimate. The method for how this adjustment should be done will vary from country to country. *However, a basic standard to uphold is that the priority for funding and procurement of ARV drugs should be to maintain the ARV drug supply for patients already on ART. Quantities to procure must be*

sufficient to cover existing patients on ART. One option to ensure this supply is to reduce the number of patients who can be expected to initiate ART within the period of the forecast, therefore reducing the quantities of ARV drugs required.

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

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

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

CONSIDERATIONS FOR QUANTIFICATION OF PEDIATRIC ARV DRUGS

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

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

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

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

3 Appendix A illustrates a national quantification in which adult and pediatric ARV drug requirements have been incorporated into the forecasted demand and into the final estimate of requirements for procurement (in this example, pediatric liquid formulations have already been rounded up to bottle size).

Step 1. Calculate the number of pediatric patients who are expected to initiate ART during the period of the forecast. This number may be based on the number of the children estimated to be on ART as a proportion of the total number of patients on ART for the forecast year. If data are available, the number may be based on an expected increase in the number of pediatric patients at ART sites in accordance with program expansion plans (e.g., plans to reach more mothers and children through expansion of PMTCT or new sites expected to initiate pediatric ART services within the forecast year).

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

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

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

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

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

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

- Liquid formulations must be calculated in milliliters (mL) at this point to determine the number of basic units required per patient per day.
- The quantities of liquid formulations required are then converted to supplier packaging sizes for procurement later in the quantification (e.g., 100 mL, 200 mL, or 240 mL bottles).

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

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

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

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

used, or another wastage rate may be used that has been otherwise agreed upon in consultation with informed stakeholders.

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

USE OF PIPELINE SOFTWARE FOR QUANTIFICATION AND PROCUREMENT PLANNING OF ARV DRUGS

Although all the previous steps have been described on the basis of using an Excel spreadsheet to capture all the assumptions and to perform all the calculations in the quantification process, a growing number of quantification software packages are available to assist with the process. As of the publication date of this guide, however, none of the available software packages reviewed[4] are able to capture all the steps outlined in this quantification guide. However, individual software does capture part of the process and would be useful if complemented by other software packages. For example, the Partnership for Supply Chain Management project is exploring the combined use of Quantimed and PipeLine software to conduct ARV drug quantification.

As an alternative to using an Excel spreadsheet for the entire process, DELIVER is moving toward the use of Excel to produce the forecast demand, followed by the use of PipeLine[5] to complete the quantification and to enable procurement planning as well. There are several benefits to this approach, including the fact that PipeLine can be used to plan and adjust shipment quantities and delivery schedules and to help identify funding needs for procurement. PipeLine is also a useful tool for sharing results among stakeholders, because it produces reports and graphs on the status of scheduled shipments, of past and projected consumption trends, and of stock levels for each product in-country.

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

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

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

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

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

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

5 PipeLine is a software package available from the DELIVER project. Visit www.deliver.jsi.com to download a free copy of the software and the user's manual.

SUMMARY OF CHALLENGES AND LESSONS LEARNED IN QUANTIFICATION OF ARV DRUGS

COMMON CHALLENGES

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

- Data on ART services and ARV drug supply are limited and, when available, are often unreliable or insufficient to be used for quantifying ARV drug requirements.
- Standard treatment guidelines may be inconsistent, may need revision, or may not have been widely disseminated to providers.
- Program targets may not take into account either the service delivery capacity to increase enrollment of new patients and to continue monitoring existing patients on ART or the supply chain capacity to finance, procure, and manage greater volumes of ARV drugs.
- Program expansion does not occur as rapidly as expected.
- Multiple sources of funding, procurement mechanisms, and distribution channels are used for ARV drugs.
- Quantification capacity is limited at the country and program levels.
- Communication and coordination are lacking among key stakeholders and implementers (i.e., policymakers, program managers, service providers, funding sources, procurement agents, and suppliers) on issues related to the selection, quantification, and procurement of ARV drug needs.
- Quantification and procurement often occur when funding becomes available, rather than as a program planning activity that identifies commodity needs and that mobilizes resources for procurement in a timely fashion. Quantification and procurement that occur when funding becomes available have led to stockouts and to expensive emergency procurements.
- Worldwide shortages of raw materials for the manufacture of ARV drugs and other limitations in supplier production capacity may need to be addressed in the quantification to identify alternate sources of supply for the required quantities of a product.

USEFUL LESSONS

The following lessons that have been learned from DELIVER's experience in conducting ARV drug quantifications in eight countries have also been incorporated into the approach to quantification that is presented in this guide.

- The quantification exercise itself is time intensive and resource intensive. Therefore, adequate time, funding, and human resources with appropriate skills to conduct the quantification exercise should be planned and should be included in the budget.
- Quantifications that currently are based on informed assumptions will become more evidence-based over time as the availability and quality of data improve through the strengthening of the LMIS.
- Quantification requires a consultative process with multiple stakeholders and implementers to inform the assumptions about the selection, quantification, and procurement of ARV drugs.
- Convening one or more consultative stakeholder meetings throughout the quantification process is recommended to clarify and review the data sources, assumptions, and methodologies used, and to reach consensus on commodity requirements and funding needs. Consultative stakeholder meetings can be a critical step toward transferring ownership of the results to in-country stakeholders. The meetings can also serve to facilitate resource mobilization, clarify expectations, and promote collaboration and coordination, especially in the event of disruptions in commodity supply that may affect availability of products for customers at service delivery points.
- The quantification should be based on realistic program plans and on available financing.
- The results of the quantification should be used to determine specific order quantities and shipment schedules for short-term procurement planning on the basis of available funding.
- The results of the quantification should also be used for medium- and long-term program planning and for resource mobilization for ART.
- The quantification should be reviewed and updated at least every six months, and procurement plans should be adjusted accordingly.

APPENDIX A

SAMPLE EXCEL SPREADSHEETS FOR QUANTIFICATION OF ARV DRUGS

PATIENT TARGETS

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

TOTAL PATIENTS 2005	
Total No. Patients	**25,000**
Percent on 1st Line Regimens	95%
Percent on 2nd Line Regimens	5%
Percent Adults	95%
Percent Children	5%
# Adults on 1st Line Regimens	22,563
# Adults on 2nd Line Regimens	1,188
# Children on 1st Line Regimens	1,188
# Children on 2nd Line Regimens	63
# HIV positive mothers on PMTCT	46,000
# Infants on PMTCT	46,000
# PMTCT mothers on NVP/labor	46,000
# PMTCT mothers on AZT	—
# PMTCT infants	46,000

TOTAL PATIENTS 2006	
Total No. Patients	**45,000**
Percent on 1st Line Regimens	93%
Percent on 2nd Line Regimens	7%
Percent Adults	95%
Percent Children	5%
# Adults on 1st Line Regimens	39,758
# Adults on 2nd Line Regimens	2,993
# Children on 1st Line Regimens	2,093
# Children on 2nd Line Regimens	158
# HIV positive mothers on PMTCT	56,000
# Infants on PMTCT	56,000
# PMTCT mothers on NVP/labor	28,000
# PMTCT mothers on AZT	28,000
# PMTCT infants	56,000

TOTAL PATIENTS 2007	
Total No. Patients	**100,000**
Percent on 1st Line Regimens	90%
Percent on 2nd Line Regimens	10%
Percent Adults	90%
Percent Children	10%
# Adults on 1st Line Regimens	81,000
# Adults on 2nd Line Regimens	9,000
# Children on 1st Line Regimens	9,000
# Children on 2nd Line Regimens	1,000
# HIV positive mothers on PMTCT	76,000
# Infants on PMTCT	76,000
# PMTCT mothers on NVP/labor	38,000
# PMTCT mothers on AZT	38,000
# PMTCT infants	76,000

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

ADULT REGIMENS YEAR 2005

YEAR 2005	Percent	No. Patients
Total No. Patients	100%	25,000
Percent on 1st Line Regimen	95%	22,563
Percent on 2nd Line Regimen	5%	1,188
Percent Adults	95%	23,750
Percent Children	5%	1,250

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

Option	2nd Line Regimens (Adults)	Percent	No. Patients
	Total No. Patients	100%	1,188
E1	TDF + ddI + LPV/r < 60kg	23%	273
E2	TDF + ddI + LPV/r > 60kg	23%	273
F1	TDF + ddI + NFV < 60kg	23%	273
F2	TDF + ddI + NFV > 60kg	23%	273
G1	ABC + ddI + LPV/r < 60kg	1%	12
G2	ABC + ddI + LPV/r >60kg	1%	12
H1	TDF + ddI + SQV + r < 60kg	3.0%	36
H2	TDF + ddI + SQV + r > 60kg	3.0%	36

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

ADULT REGIMENS YEAR 2005
PHASING-IN RATES

1ST LINE REGIMENS

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

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

2ND LINE REGIMENS

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

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

ADULT REGIMENS YEAR 2006

YEAR 2006	Percent	No. Patients
Total No. Patients	100%	45,000
Percent on 1st Line Regimen	93%	39,758
Percent on 2nd Line Regimen	7%	2,993
Percent Adults	95%	42,750
Percent Children	5%	2,250

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

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

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

ADULT REGIMENS YEAR 2006
PHASING-IN RATES

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

PHASING-IN OF NEW PATIENTS ON 1ST LINE REGIMENS

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

2nd LINE REGIMENS		Existing Pts. (Year 2005)	New Pts.	Total New (New + Default)
Phasing-in 2nd Line Regimens		1,188	1,805	1,864
Default Rate 2nd Line Regimens	5%	59		

PHASING-IN OF NEW PATIENTS ON 2ND LINE REGIMENS

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

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

ADULT REGIMENS YEAR 2007

YEAR 2007	Percent	No. Patients
Total No. Patients	100%	100,000
Percent on 1st Line Regimen	90%	81,000
Percent on 2nd Line Regimen	10%	9,000
Percent Adults	90%	90,000
Percent Children	10%	10,000

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

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

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

ADULT REGIMENS YEAR 2007
PHASING-IN RATES

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

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

2nd LINE REGIMENS	Percent	Existing Pts. (Year 2006)	New Patients	Total New (New + Default)
Phasing-in 2nd Line		2,993	6,008	6,157
Default Rate 2nd Line	5%	150		

PHASING-IN OF NEW PATIENTS ON 2ND LINE REGIMENS				
Phasing In by %	**%**	**# Days**	**Patients**	**Patient-days**
Quarter 1	15%	365	924	337,103
Quarter 2	25%	275	1,539	423,302
Quarter 3	25%	184	1,539	283,228
Quarter 4	35%	92	2,155	198,259

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

QUALITY REQUIRED (ADULTS) FORECAST YEARS 2005–2007

		YEAR 2005				YEAR 2006				YEAR 2007			
Option	REGIMENS	No. Patients	Patient-days	Units per Patient-day	No. Basic Units Required	No. Patients	Patient-days	Units per Patient-day	No. Basic Units Required	No. Patients	Patient-days	Units per Patient-day	No. Basic Units Required
	1st Line Regimens (Adults)												
A1	d4T (30mg)+3TC+NVP	5,641	1,112,049	2	2,224,098	11,132	3,316,376	2	6,632,752	22,680	6,707,686	2	13,415,371
A1	3TC/d4T (30)		84,609	2	169,219		82,372	2	164,744		173,219	2	346,437
A1	NVP 200mg			1	84,609			1	82,372			1	173,219
A2	d4T (40mg)+3TC+NVP	4,513	889,639	2	1,779,279	9,939	2,889,817	2	5,779,634	23,490	6,730,965	2	13,461,930
A2	d4T (40)/3TC		67,688	2	135,375		81,403	2	162,806		203,259	2	406,519
A3	NVP 200 mg			1	67,688			1	81,403			1	203,259
B	(AZT/3TC + NVP) Aspen co-pack	9,476	1,868,243	2	3,736,485	13,518	4,384,289	2	8,768,578	24,300	7,403,087	2	14,806,174
C1	d4t (30mg)/3TC	1,128	222,410	2	444,820	1,988	608,648	2	1,217,297	4,050	1,197,801	2	2,395,602
C1	EFV 600mg			1	222,410			1	608,648			1	1,197,801
C2	d4T (40)/3TC	1,128	222,410	2	444,820	1,988	608,648	2	1,217,297	4,050	1,197,801	2	2,395,602
C2	EFV 600mg			1	222,410			1	608,648			1	1,197,801
D	AZT/3TC from Aspen co-pack	677	133,446	2	266,892	1,193	365,189	2	730,378	2,430	718,681	2	1,437,361
D	EFV 600mg			1	133,446			1	365,189			1	718,681

QUALITY REQUIRED (ADULTS) FORECAST YEARS 2005–2007 (*CONTINUED*)

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

QUALITY REQUIRED (ADULTS) FORECAST YEARS 2005–2007 (*CONTINUED*)

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

PEDIATRIC REGIMENS YEAR 2005

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

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

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

PEDIATRIC REGIMENS YEAR 2005 *(CONTINUED)*

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

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

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

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

PEDIATRIC REGIMENS YEAR 2006

Option	1st Line Regimens (Children)	Percent	No. Patients	New Patients
	Total No. Patients		2,093	
	Percentage under 3 years, <12kg		70%	
P1	AZT+3TC+NVP	50%	732	317
P2	d4T+3TC+NVP	50%	732	317
	Percentage >3-12 yrs, 12-30kgs		30%	
P3	(AZT/3TC+NVP) Aspen co-pack	60%	377	163
P4	d4T30/3TC/NVP	20%	126	54
P5	d4T30/3TC+EFV	20%	126	54

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

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

PEDIATRIC REGIMENS YEAR 2006 *(CONTINUED)*

PHASING-IN RATE FOR NEW PATIENTS, BY REGIMEN		
Phasing-in by Regimen	**Existing Patients**	**New Patients**
1st Line Regimens	1,188	905
2nd Line Regimens	63	95

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

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

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

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

PEDIATRIC REGIMENS YEAR 2007

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

Option	2nd Line Regimens (Children)	Percent	No. Patients	New Patients
	Total No. Patients		1,000	
	Percentage <12kgs		10%	
P6	ABC+3TC+NFV	100%	100	91
	Percentage 12-30kgs tabs		85%	
P7	ABC+3TC+LPV/r	70%	595	538
P8	ABC+3TC+NFV	30%	255	231
	Percentage 12-30kgs (susp)		5%	
P9	ABC+3TC+LPV/r	70%	35	32
P10	ABC+3TC+NFV	30%	15	14

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

PEDIATRIC REGIMENS YEAR 2007 (*CONTINUED*)

PHASING-IN RATE FOR NEW PATIENTS, BY REGIMEN		
Phasing-in by Regimen	**Existing Patients**	**New Patients**
1st Line Regimens	2,093	6,908
2nd Line Regimens	158	843

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

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

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

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

ASSUMPTIONS FOR PEDIATRIC QUANTIFICATION

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

All ages 3–12 years will take tablets and capsules.

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

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

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

Pediatric Dosing Schedule	Drug Formulation	Units/ Patient per Day	Bottles/ Patient Month PMTCT	Bottles/ Patient per Month	ASSUMPTIONS
< 3 years	oral suspensions, syrups				Assume all 3-year-old children are 12 kg and body surface .3 m^2 - .5 m^2
AZT 240mg/m2/dose bid	AZT 10mg/ml syrup			4	Body surface of 1 m^2 = 30 kg
GSK	200ml			4	
Combino pharm	200ml			4	
GPO	200ml/60ml		13	4	if bottle of 60 ml supplied by GPO
3TC 4 mg/kg/dose bid	3TC 10mg/ml oral suspension			2	
3TC 4 mg/kg/dose bidCipla (50mg/ml; 100ml bottle				2	Q per month shall vary depending on kg. Below 10 kg one bottle sufficient
	100ml				
3TC 4mg/kg/dose bid GSK 10mg/ml susp. 240 ml bottle				3	Q per month shall vary depending on kg. Below 10 kg two bottles sufficient
NVP 200mg/m^2/dose od x 14 days, then NVP 200mg/m^2/dose bid	NVP 10mg/ml oral suspension			3	NVP 2.5 bottles of 240ml per patient rounded up to 3 bottles
GPO 10mg/ml oral susp	60ml			10	
BI 10mg/ml susp	240ml			3	

ASSUMPTIONS FOR PEDIATRIC QUANTIFICATION (*CONTINUED*)

Pediatric Dosing Schedule	Drug Formulation	Units/ Patient per Day	Bottles/ Patient Month PMTCT	Bottles/ Patient per Month	ASSUMPTIONS
Cipla	100ml and 25 ml		24	6	24 bottles/month if 25 ml bottles supplied
					If one infant dose = 0.6ml NVP, then # doses per bottle = # infants that can be treated
					If 25ml bottle = 41 infants can receive NVP prophylaxis,
					If 60ml bottle = 100 infants can receive prophylaxis
					If 100ml bottle = 166 infants. If 240 ml bottle = 400 infant doses
					Question is, how many mothers (assuming 1 infant per mother) will actually receive NVP for PMTCT in year 2005, year 2006? Then figure out number of bottles needed. Short shelf life (expiry dates) needs to be taken into account for huge wastage, esp the 240 ml bottles.
d4T 1mg/kg/dose bid	d4T 1mg/ml PFR 200mg per bottle			5	
	GPO 1 mg/ml;bottle 60 ml			12	
	GPO 5 mg/ml;bottle 60 ml			3	Needed 2.5, rounded to 3 bottles
	BMS 200ml bottle			5	Comes in powder of 1mg/ml
ABC 8mg/kg/dose bid	ABC 20mg/ml oral solution GSK			2	
ddI 90mg/m^2/dose bid	ddI 10mg/ml PFR 2g (< 1 year old)			1	Only < 1 year old take ddI 10mg/ml oral solution (1 bottle = 2,000mg)
	BMS				

ASSUMPTIONS FOR PEDIATRIC QUANTIFICATION (*CONTINUED*)

Pediatric Dosing Schedule	Drug Formulation	Units/ Patient per Day	Bottles/ Patient Month PMTCT	Bottles/ Patient per Month	ASSUMPTIONS
NFV 75mg/kg/dose bid < 1 year old	NFV 250mg tab crushed	5			NFV 250mg tabs to be used for all < 3 years and 3-13 years
Roche, Switzerland, powder for susp. 50mg/g; 144g				8	8 bottles needed if child 12 kg
LPV/r (12mg/kgLPV+3mg/kg RTV bid)	LPV/r 80mg/20mg/ml syrup			1	LPV/r only for children > 6 months
Abbot laboratories, 20mg/80mg/ml; 60 ml bottle					1 bottle is the equivalent of a pack of 5 x 60ml bottles
4–13 years	capsules, tablets				
AZT 240mg/m^2/dose bid	AZT 100mg capsule 12kg - 30kg				Use AZT 100mg capsule or use only AZT/3TC tablets
	AZT300mg/3TC 150mg 1/2 tablet bid <30kg	1			80% pts <30kg
	AZT300mg/3TC 150mg 1 tablet bid >30kg	2			20% pts >30kg
3TC 4 mg/kg/dose bid	3TC 150mg tablet	2			
NVP 200mg/m^2/dose od x 14 days	NVP 200mg tablet	1			
d4T/3TC/NVP	30mg/150mg/200mg, 1/2 tab bid	1			Assume kids will get half adult dose twice a day
d4T/3TC fixed dose	d4T/3TC 30mg/150mg 1/2 tab bid	1			Assume kids will get half adult dose twice a day

ASSUMPTIONS FOR PEDIATRIC QUANTIFICATION (*CONTINUED*)

Pediatric Dosing Schedule	Drug Formulation	Units/ Patient per Day	Bottles/ Patient Month PMTCT	Bottles/ Patient per Month	ASSUMPTIONS
EFV 50mg caps	EFV 50mg, 20-29kg, 3caps od	3			Based on MSF dosing schedule, between 15-29kg, it's 1, 2, and 3
					50mg caps od, we took the highest dose in the weight band
ABC 8mg/kg/dose bid	ABC 300mg tablet	2			
ddI 90mg/m^2/dose bid	ddI 25mg, 50mg, 100mg tablet bid	2			ddI 25mg, 50mg, 100mg tablets for 1-13 years old
NFV 60mg/kg/dose bid (1-13 years old)	NFV 250mg tab crushed	14			NFV 250mg tabs to be used for all < 3 years old and 3-13 years old
LPV/r (12mg/kgLPV+3mg/kg RTV bid)	LPV/r 133.3mg/33.3mg capsule	4			12 kg = LPV/r 133.3mg/33.3 mg one capsule od
					20kg - 40kg = LPV/r 133.3mg/33.3mg two capsules bid
					> 40kg = LPV/r 133.3mg/33.3mg 3 capsules bid

QUANTITY REQUIRED (CHILDREN) FORECAST YEARS 2005–2007

Assume USG funds will be used to purchase pediatric formulations, so use originator bottle/patient/month number whenever possible
We did not take into account two options that were used for adults: a) dosing was calculated for the highest weight within a weight band, assuming some would be wasted; and b) no half dose for the 15 day step-up period for Nevirapine was calculated; instead the full dose for the full period was used.

		YEAR 2005							YEAR 2006							YEAR 2007						
Option	1st Line Regimens	Total Patients	Patient-days	Patient-months	Units per Patient-day	Bottles per Patient-month	Total Units /tabs/ caps	Bottles per Year	Total Patients	Patient-days	Patient-months	Units per Patient-day	Bottles per Patient-month	Total Units /tabs/ caps	Bottles per Year	Total Patients	Patient-days	Patient-months	Units per Patient-day	Bottles per Patient-month	Total Units /tabs/ caps	Bottles per Year
	Under 3yrs, <12kg																					
P1	AZT syrup 10mg/ml	416	72,464	2,415		4		9,662	732	224,239	7,475		4		29,899	3,150	916,131	30,538		4		122,151
	3TC syrup 10mg/ml					3		7,246					3		22,424					3		91,613
	NVP syrup 10mg/ml					3		7,246					3		22,424					3		91,613
	Under 3yrs, <12kg																					
P2	d4T syrup 1mg/ml powder for syrup	416	72,464	2,415		5		12,077	732	224,239	7,475		5		37,373	3,150	916,131	30,538		5		152,689
	3TC syrup 10mg/ml					3		7,246					3		22,424					3		91,613
	NVP syrup 10mg/ml					3		7,246					3		22,424					3		91,613
	Over 3-12yrs, 12-30kg																					
P3	(AZT/3TC + NVP) Aspen co-pack	214	37,267		1		37,267		377	115,323		1		115,323		1,620	471,153		1		471,153	
P4	d4T/3TC/NVP (30mg)	71	12,422		1		12,422		126	38,441		1		38,441		540	157,051		1		157,051	
P5	d4T/3TC (30mg)	71	12,422		1		12,422		126	38,441		1		38,441		540	157,051		1		157,051	
	EFV 50mg cap				3		37,267					3		115,323					3		471,153	
	2nd Line Regimens																					
	Under 3yrs, <12kgs																					

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

		YEAR 2005							YEAR 2006							YEAR 2007						
Option	1st Line Regimens	Total Patients	Patient-days	Patient-months	Units per Patient-day	Bottles per Patient-month	Total Units /tabs/ caps	Bottles per Year	Total Patients	Patient-days	Patient-months	Units per Patient-day	Bottles per Patient-month	Total Units /tabs/ caps	Bottles per Year	Total Patients	Patient-days	Patient-months	Units per Patient-day	Bottles per Patient-month	Total Units /tabs/ caps	Bottles per Year
P6	ABC+3TC+NFV																					
	ABC 20mg/ml oral solution	6	918	31		2		61	16	4,457	149		2		297	100	26,473	882		2		1,765
	3TC 10mg/ml susp 240ml bottle	6	918			2		61	16	4,457			2		297	100	26,473			2		1,765
	NFV 50mg/g powder for susp;144g	6	918			8		245	16	4,457			8		1,188	100	26,473			8		7,060
	12-30kgs (tabs)																					
P7	ABC+3TC+LPV/r																					
	ABC 300mg tablet	37	5,465		2		10,929		94	26,518		2		53,035		595	157,516		2		315,032	
	3TC 150 mg tablet	37	5,465		2		10,929		94	26,518		2		53,035		595	157,516		2		315,032	
	LPV/r 133.3/33.3 caps	37	5,465		14		76,506		94	26,518		14		371,247		595	157,516		14		2,205,222	
P8	ABC+3TC+NFV																					
	ABC 300mg tablet	16	2,342		2		4,684		40	11,365		2		22,729		255	67,507		2		135,014	
	3TC 150mg tablet	16	2,342		2		4,684		40	11,365		2		22,729		255	67,507		2		135,014	
	NFV 250mg tab	16	2,342		4		9,368		40	11,365		4		45,459		255	67,507		4		270,027	
	12-30kgs (susp)																					
P9	ABC+3TC+NFV																					
	ABC 20mg/ml oral susp	1	138	5		2	-	9	2	1,104	37		2	-	74	15	8,116	271		2		541
	3TC 10mg/ml susp 240ml bottle	1	138	5		3		14	2	1,104	37		3		110	15	8,116	271		3		812
	NFV 50mg/g powder for susp;144g	1	138	5		8		37	2	1,104	37		8		294	15	8,116	271		8		2,164

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

		YEAR 2005							YEAR 2006							YEAR 2007						
Option	1st Line Regimens	Total Patients	Patient-days	Patient-months	Units per Patient-day	Bottles per Patient-month	Total Units /tabs/ caps	Bottles per Year	Total Patients	Patient-days	Patient-months	Units per Patient-day	Bottles per Patient-month	Total Units /tabs/ caps	Bottles per Year	Total Patients	Patient-days	Patient-months	Units per Patient-day	Bottles per Patient-month	Total Units /tabs/ caps	Bottles per Year
P10	ABC+3TC+LPV/r																					
	ABC 20mg/ml oral solution	2	321	11		2		21	6	1,125	37		2		75	35	5,121	171		2		341
	3TC 10mg/ml susp 240ml bottle	2	321	11		3		32	6	1,125	37		3		112	35	5,121	171		3		512
	LPV/r 80mg/20mg/ml	2	321	11		1		11	6	1,125	37		1		37	35	5,121	171		1		171
			-																			
	PMTCT Prophylaxis (Infants)																					
Q	NVP 10mg/1ml oral susp 240 ml bottle	46,000	46,000		1			144	28,000	28,000		0.5			87.5	38,000			0.5			119
R	AZT syrup 10mg/1ml 200 ml bottle								28,000	28,000			1		28,000	38,000				1		38,000

ARV DRUG QUANTITIES REQUIRED 2005–2007

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

(*CONTINUED*)

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

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