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GUIDE FOR QUANTIFYING HIV TESTS



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DELIVER
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GUIDE FOR QUANTIFYING HIV TESTS

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Abstract

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

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ACRONYMS

AIDS	acquired immunodeficiency syndrome
AMAD	average monthly adjusted demand
AMQR	average monthly quantity required
ANC	antenatal care
ART	antiretroviral therapy
ARV	antiretroviral drugs
CDC	Centers for Disease Control and Prevention
DHS	Demographic and Health Survey
ELISA	enzyme-linked immunosorbent assay
HIV	human immunodeficiency virus
LMIS	logistics management information system
MOH	Ministry of Health
MTCT	mother-to-child transmission
NAC	National AIDS Committee
NACP	National AIDS Control Program
NGO	nongovernmental organization
OI	opportunistic infection
PCR	polymerase chain reaction
PEP	post-exposure prophylaxis
PEPFAR	President's Emergency Plan for AIDS Relief
PMTCT	prevention of mother-to-child transmission
RTD	rapid test devices
STG	standard treatment guidelines
STI	sexually transmitted infection
TB	tuberculosis
UNAIDS	United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
VCT	voluntary counseling and testing
WHO	World Health Organization

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PREFACE

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

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

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

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

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

This guide for quantifying HIV tests draws from the collective experience of DELIVER logistics advisors who have been involved in a range of activities to improve management of the supply chains for HIV/AIDS commodities in several countries that are hardest hit by the epidemic. The list of countries includes Ghana, Kenya, Malawi, Mozambique, Nepal, Nigeria, South Africa, Tanzania, Uganda, Ukraine, Zambia, and

Zimbabwe. DELIVER's experience indicates that two of the most critical supply chain interventions for HIV testing and counseling programs at this time are the need to:

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

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

INTRODUCTION TO QUANTIFICATION

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

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

DEFINITION OF TERMS

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

CUSTOMER

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

CUSTOMER DEMAND

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

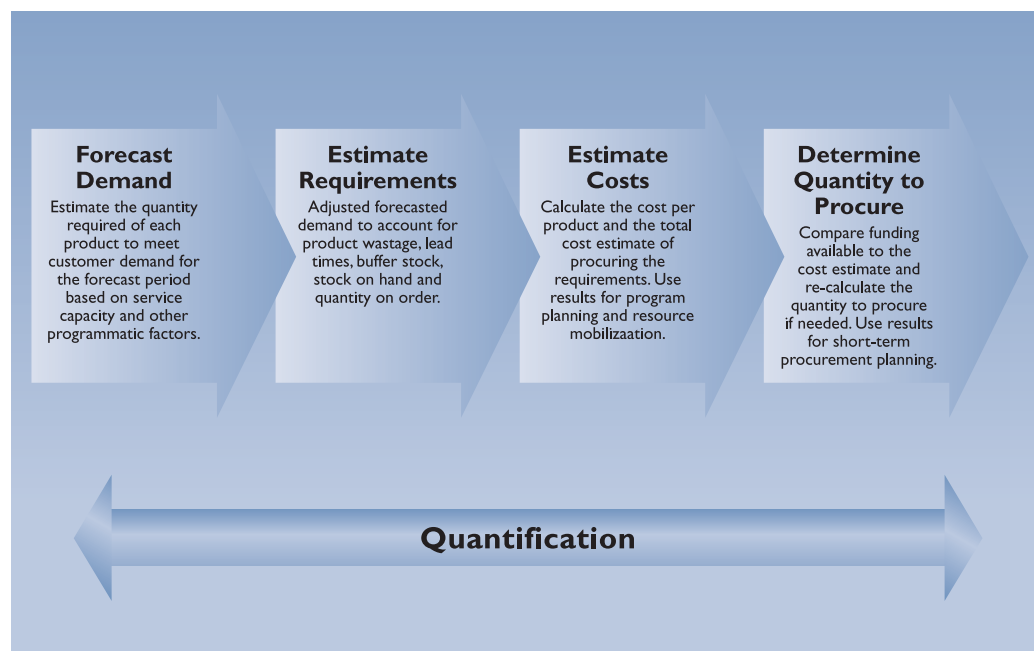
PRODUCT WASTAGE

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

STEPS IN QUANTIFICATION

Figure 1 represents the steps in the quantification process.

Figure 1. The Quantification Process



FORECASTING DEMAND

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

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

ESTIMATING REQUIREMENTS

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

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

ESTIMATING COSTS

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

DETERMINING QUANTITY TO PROCURE

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

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

FORECASTING METHODOLOGIES

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

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

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

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

THE CONSUMPTION-BASED METHODOLOGY

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

THE ADJUSTED CONSUMPTION METHODOLOGY

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

THE MORBIDITY-BASED METHODOLOGY

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

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

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

THE IMPORTANCE OF STANDARDIZATION IN QUANTIFICATION

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

- Each purpose of use (e.g., VCT, PMTCT, Blood Safety) may require a different protocol that is based on HIV prevalence, purpose of the testing, and number of different tests available in the program. For example, for unlinked blood safety testing, ensuring the safety of the blood supply is the highest priority, so all positive tests are automatically discarded without retesting. Such a procedure will require a different protocol from that used for VCT, in which case, it may be important to confirm that the first positive test result is truly a positive result or whether a second test or a third test might be required.
- The testing protocols are a guide for the individuals administering the tests. Given that programs are in the process of expanding and that the number of skilled and experienced service providers who perform HIV testing is small relative to the number of testing sites, the protocols are an essential tool for helping new providers provide quality test results to clients.
- HIV test technology is evolving rapidly, with new tests being developed and an array of test brands already available on the international market. Not all tests, however, perform equally in producing highly sensitive or specific results. For diagnostic testing, usually a combination of tests are used to maximize the service provider's ability to provide the most accurate test result, in the shortest amount of time, at the most optimal cost. Without standard protocols in place, providers may choose expensive and ineffective tests, which might result in clients receiving incorrect test results and in compromising the credibility of the entire program.

Standardization of testing protocols is especially critical in the context of quantification. In the absence of quality logistics data, quantification will likely be conducted using the morbidity-based methodology. To enhance the accuracy of the quantification using this method, standard testing protocols must exist and must be clearly documented and disseminated. Because of the fact that tests are often conducted in combination, quantification is extremely challenging without the existence of standard protocols and can result in significant quantities of wasted tests. DELIVER's experience has been that the lack of standardization of testing protocols can significantly delay the quantification and procurement processes, thus compromising product availability to programs.

BACKGROUND

Before one quantifies HIV test requirements, it is important to have a basic knowledge of the characteristics of HIV tests and the ways in which they are used for HIV testing.

TYPES OF HIV TESTS

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

TABLE 1. HIV TESTS

Test	Sites of Use	Advantages	Limitations
Simple/rapid assay (Rapid test device, or RTD)	Small labs, VCT sites, PMTCT sites, STI, and TB clinics, emergency care centers	<ul style="list-style-type: none"> • Easy to use and interpret test results • Results within 10–30 minutes • No minimum volume of tests required • Requires minimal equipment • Does not require highly skilled staff members • Has many newer tests that can be stored at room temperature • When used in combination, results that are as reliable as ELISAs • Can be used on various types of specimens, including whole blood • Oral fluid tests that have been developed recently, that are noninvasive, and that do not require sharps • Can be used to do on-site or point-of-care testing 	<ul style="list-style-type: none"> • Small-scale testing • Considerable variation in sensitivity; however, this variation often depends on the type of specimen (i.e., whole blood, serum, oral fluid) • Cold chain sometimes required • May cost more per individual test • Some products that are less sensitive for sero-convertors • Use of rapid tests at multiple sites in resource-poor countries that will pose quality assurance challenges

Test	Sites of Use	Advantages	Limitations
enzyme linked immunosorbent assays (ELISA)	Large hospitals, blood banks, or reference laboratories	<ul style="list-style-type: none"> Highly sensitive, especially for picking up sero-convertors Batch testing Can be automated Easier to conduct quality assurance testing, because tests are performed in fewer, high-volume laboratories 	<ul style="list-style-type: none"> Requires more time to obtain results (1–3 hours) and even longer if not at point of care Need sophisticated equipment and equipment maintenance Cold chain always required Need minimum volume of tests for maximum efficiency Requires skilled technicians
Western blot	Large teaching hospitals, reference laboratories, and the National Reference Laboratory	<ul style="list-style-type: none"> The “Gold Standard” Detects all antibodies present 	<ul style="list-style-type: none"> Requires skilled and experienced personnel Nonroutine test (small batches only, usually <10 in a batch used for research and for clarifying indeterminate results)

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

PRIMARY USES OF HIV TESTS

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

ENSURING BLOOD SAFETY

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

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

VOLUNTARY COUNSELING AND TESTING

Voluntary HIV counseling and testing (VCT) has been the primary diagnostic testing strategy to date in expanding programs. VCT is often considered a pivotal strategy for HIV/AIDS prevention, care, support, and treatment activities. Individuals who test negative can take appropriate measures to avoid becoming infected. Individuals who test positive can access treatment, care, and support services, including condom distribution,

PMTCT, prevention, and clinical management of HIV-related illnesses, STI and TB control, psychosocial and legal support, and antiretroviral therapy, if available.

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

PREVENTION OF MOTHER-TO-CHILD TRANSMISSION

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

TESTING OF HIV-EXPOSED BABIES

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

HIV COUNSELING AND TESTING

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

Quantification for HCT will yield a higher number of tests because 100 percent of clients will be receiving counseling and will be offered testing. Although not all clients will accept testing, evidence from PMTCT programs that have chosen to implement “opt-out” testing suggests that more than 80 percent of clients will opt for testing after receiving counseling.

SENTINEL SURVEILLANCE (SS)

HIV testing is conducted on select population subgroups to enable health officials to describe the HIV/AIDS epidemic in a country, to plan and advocate for responses, and to evaluate the effectiveness of the responses.

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

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

OTHER USES

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

HIV TESTING PROTOCOLS

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

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

TABLE 2. SERIAL PROTOCOLS

Protocol	Tests	If, then	Examples
S1	A	If test A is positive, the result is positive. If test A is negative, the result is negative.	Unlinked Blood Safety Program
S2	A B	If test A is positive, run test B. If test B is positive, the result is positive.	PMTCT or VCT program, with third test referral to the higher level
S3	A B C	If test A is positive, run test B. If test B is positive, the result is positive. If test B is negative, run test C. If test C is positive, the result is positive. If test C is negative, the result is negative.	PMTCT or VCT program, all testing on site

TABLE 3. PARALLEL PROTOCOLS

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

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

STEPS IN THE QUANTIFICATION

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

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

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

PREREQUISITES TO QUANTIFICATION

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

DEFINE THE SCOPE AND THE PURPOSE OF THE QUANTIFICATION

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

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

- National-level quantification across all purposes of use to meet the needs of the whole country
- Quantifications by different sector (public sector, nongovernmental [NGO] organizations, or private sector), for the same or different purposes of use
- Quantifications by program or by purpose of use (e.g., a quantification for HIV test requirements for the public sector VCT and PMTCT programs, or for VCT in the NGO and Mission sector only)
- Quantifications by target population (e.g., to support VCT for marginalized population groups, such as intravenous drug users or commercial sex workers)

- Quantifications by geographic region (e.g., HIV counseling and testing services may exist or may be supported in certain regions of the country and not in other regions)
- Quantifications by funding source (government or donor organizations that procure different products may require separate quantifications)
- Quantifications by supply chain (quantification for products that may be supplied by a particular source with its own procurement and distribution systems)

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

- Is the quantification for resource mobilization in order to inform donors about funding requirements and to advocate for resources for HIV test kit procurement?
- Is the quantification for planning purposes in order to estimate national HIV test kit requirements and to assess the stock status of the in-country supply pipeline so that supply imbalances can be identified and corrected?
- Is the quantification to support an estimate of commodity procurement, storage, and distribution costs?

The quantification should answer the following key questions:

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

DESCRIBE THE PROGRAM

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

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

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

DETERMINE THE PERIOD OF THE DEMAND FORECAST

Medium-term forecasts of HIV test requirements for two to five years are recommended to assist in program planning and in mobilizing financial resources for procurement of HIV tests to support program expansion. The quantification and the costing of commodity requirements for procurement with available funds for a one-year period are recommended for short-term procurement planning and should include specific quanti-

EXAMPLE 1: ONE SUPPLY CHAIN, ONE QUANTIFICATION

In country **X** in the public sector, the funds for test kits for blood safety are provided by the government using a Global Fund grant; the funds for test kits for VCT and PMTCT are provided both by the government Global Fund grant and by the President's Emergency Plan for AIDS Relief (PEPFAR); and the funds for test kits for sentinel surveillance (SS) are provided by PEPFAR through the Centers for Disease Control and Prevention (CDC). However, all the kits are stored and distributed through the public sector's MOH supply chain as part of the national HIV/AIDS program. In this case, you would forecast demand separately for each of those four purposes and then would aggregate the overall quantities required to determine the total quantities of kits required by the MOH.

EXAMPLE 2: TWO SUPPLY CHAINS, TWO QUANTIFICATIONS

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

ties 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 HIV testing services 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 changes in services provided and quantities of commodities used.

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

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

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

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

COLLECT THE REQUIRED DATA

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

The following steps may be useful as a guide:

- Step 1. Identify the type of program (e.g., MOH, nongovernmental organization, Mission, or religious, or pilot or research).
- Step 2. List all HIV testing services provided or those services relevant for the quantification (HCT, PMTCT, VCT, BS, SS).
- Step 3. Describe the model of care (the level and type of facilities where HIV testing services are provided such as a primary, secondary, tertiary, community-based, or outreach facility). Describing how the testing services are structured is a particularly important step for HIV test quantification, given the potential overlap in use of tests between various services. Questions that will provide general background information for defining the structure of services are listed in more detail in appendix A.
- Step 4. Ascertain national guidelines for each HIV testing service identified, including recommended testing protocols or required standard testing protocols.
- Step 5. Verify that all HIV tests required in the standard testing protocols are approved and registered for importation and for use in the country.
- Step 6. Identify suppliers for each HIV test kit.

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

- Step 1. Identify all sources of financing for HIV tests (the government, international donor agencies, foundations, and pharmaceutical company donation programs such as Abbott's Determine®).
- Step 2. Determine the amount and duration of each financial commitment for HIV test kit procurement. Identify specifically when funds will be available for use.
- Step 3. Identify the procurement mechanisms and suppliers for each product (national bulk procurement, procurement through local distributors, or direct donation of product).
- Step 4. Verify local and international pricing information for each type of test kit.
- Step 5. Identify any cost-recovery or cost-sharing mechanisms in effect. Are there any costs associated with HIV testing services (co-pay, free, sliding fee, partial subsidy)? What are the likely implications of the costs on client uptake of testing services?
- Step 6. Identify any restrictions on financing regarding the types of tests that can be procured (for example, funds from the Global Fund to Fight AIDS, Tuberculosis, and Malaria might be used only to procure HIV tests from WHO pre-qualified suppliers, but PEPFAR funds might only allow for HIV tests to be procured from an approved FDA or CDC list).

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

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

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

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

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

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

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

Step 6. Confirm facility order intervals.

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

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

Key informants to interview include the following:

- Head of the National AIDS Control Program NACP (usually within the MOH)
- Heads of the various HIV testing program services, including national laboratory services, blood safety services and transfusion services, VCT and PMTCT services, national hospital services, tertiary care hospitals, local blood collection facilities (in decentralized environments), etc.
- Head of the National AIDS Committee
- Service providers from NGOs providing HIV counseling and testing services
- Donors involved in HIV/AIDS support
- Procurement agents
- Service providers involved in VCT, PMTCT, SS, blood collection, and blood transfusions
- Private sector suppliers and laboratories

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

- National HIV/AIDS policy or strategy papers
- National HIV testing, VCT, PMTCT, or Blood Safety Guidelines
- MOH or NACP annual reports or plans
- Budgetary documents or proposals, including those documents or proposals for the Global Fund, the World Bank, and PEPFAR

- Demographic and Health Surveys (which increasingly include useful information on provision and on use of HIV testing services)
- National essential drugs lists, particularly for laboratory reagents, for supplies, and for materials
- HIV testing protocols
- Health management information system (HMIS) reports
- Logistics records and reports on HIV test kit procurement, distribution, consumption, and balances
- Special reports, as well as studies from other cooperating agencies and from donors.

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

FORECAST DEMAND

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

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

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

ADJUST DEMAND FOR QUALITY CONTROL

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

ADJUST DEMAND FOR WASTAGE

To fill the pipeline and to ensure a full supply of HIV tests, it is important to adjust the demand to compensate for tests that will not reach the service delivery point. The wastage factor is the estimated percentage of a

brand of test that will become damaged, be unusable, be spilt, or be found defective. Also, if provider-initiated HCT is not a defined and acceptable purpose of use within the program, the wastage factor for the other purposes might have to be increased because tests intended for uses such as VCT, PMTCT, blood safety, or SS might be diverted to this kind of HCT.

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

$$\begin{aligned} & (\text{Demand}) \times [1 + (\text{quality control factor} + \text{wastage factor})] \\ & = \text{demand adjusted for quality control and wastage} \end{aligned}$$

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

DETERMINE HIV TESTING CAPACITY AND ADJUST DEMAND, IF NECESSARY

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

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

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

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

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

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

TO CALCULATE SERVICE CAPACITY FOR EACH PURPOSE OF USE, APPLY THE FOLLOWING CALCULATION:

$$\begin{aligned} & (\text{Total number of technicians conducting HIV testing}) \times \\ & (\text{number of days per year on average that a technician} \\ & \quad \text{will conduct HIV testing for the specified use}) \times \\ & (\text{average number of tests a technician will conduct} \\ & \quad \text{per day for the specified use}) \\ & = \text{HIV testing capacity for that use.} \end{aligned}$$

ESTIMATE REQUIREMENTS

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

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

1. What is the average monthly adjusted demand for each brand of test?
2. What is the average lead time in months for each brand of HIV test to be used in the program? (*Lead time* is defined as the time from when an order is placed until the tests arrive and are available for use. If the test kits are being imported, be sure to include time for customs clearance and inspection, as well as for quality check if the kits are to be assessed before being released for use.)
3. What is the desired level of buffer stock in months for each brand of test?
4. What is the volume of each brand of HIV test kit to be stored and distributed?
5. Which of the HIV test kits requires cold storage?
6. What is the volume of available cold storage and room temperature storage space at the level at which the HIV tests will enter the program?
7. What is the likely number of shipments of each brand of HIV test per year?
8. How much usable stock of each brand of HIV test is on hand at all levels of the system? (Subtract the number of tests on hand that will likely expire before use at current usage rates from the stock-on-hand figure.)
9. What quantity of each brand of HIV test is already on order from the suppliers? (Subtract the number of tests on order that will likely expire before use at current usage rates from the stock-on-order figure.)

The following calculations are used to estimate quantities required:

- a. $(\text{Adjusted demand quantity for each brand of HIV test for one year}) \div (12 \text{ months})$
= average monthly adjusted demand (AMAD) for each brand of HIV test.
- b. $(\text{Desired buffer stock for each brand of HIV test in months})$
 $\times (\text{AMAD for each brand of HIV test}) = \text{buffer stock for each brand of test.}$
- c. $(\text{Adjusted demand quantity for each brand of HIV test for one year})$
 $+ (\text{buffer stock for each brand of test}) = \text{Quantities Required.}$

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

Calculations for Storage and Distribution Space Requirements. At some point during the quantification, additional adjustments in the requirements estimate may be required to adjust for the volume of product that can be adequately stored and distributed to ensure the quality and security of the HIV test supply. This adjustment does not always have to occur at this point and can also take place during procurement planning and shipment scheduling. However, it is very important that a calculation is made for the cool (2–8°C) storage space and room temperature (8–30°C) storage space requirements for the HIV tests that will be procured.

The volume of incoming shipments can be calculated using DELIVER's *HIV Test Fact Sheets* (2006) or other sources of information on packaging and shipment sizes of HIV test kits on the market. Volumes can then be compared to actual storage space that is available in the country, especially at the point at which the test kits will enter the supply chain. The estimates of shipment volume and storage capacity are particularly important for products that require refrigeration, because that space is often at a premium.

Calculating storage space requirements entails the following steps:

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

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

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

$$\begin{aligned} & (\text{quantity required for each brand}) \times (\text{number of each brand of tests in a kit}) \\ & \times (\text{volume of one HIV test kit of each brand required}) \\ & = \text{total volume for each brand of HIV test.} \end{aligned}$$

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

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

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

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

- e. Compare the volume per shipment of tests requiring cold storage and tests requiring under 30°C to the available cold storage space of both types.
- f. If the available cold storage space and the available under 30°C storage space are the same as or larger than the expected shipment volumes, storage at entry level does not pose a constraint.
- g. If the available cold storage space or the available under 30°C storage space is less than the volume of each shipment, advise the program managers that the storage space or the number of shipments must be increased so that each shipment can be properly stored on arrival.

Advisors or individuals who are engaged in preparing the quantification are strongly advised to verify as part of the process that adequate security measures exist for the volume of HIV tests that are to be stored and distributed at the different levels of the program and at HIV counseling and testing service sites. Adequate security measures will minimize obstacles once the products arrive in country.

ESTIMATE COSTS

To calculate financial requirements for the quantities of tests required, the following information is needed:

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

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

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

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

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

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

DETERMINE QUANTITY TO PROCURE

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

- If sufficient funding is available, the final quantity to procure of each HIV test kit will be the same as the requirements estimate. In the current environment of increasing financial resources for HIV/AIDS commodity procurement, funding may be adequate to ensure full supply for the estimates of HIV test

requirements, provided that service delivery and supply chain capacity exist. Financial resources could also surpass program capacity to expand quality HIV counseling and testing services and to ensure a reliable supply of HIV tests. In that case, additional quantities of HIV tests should not be procured because such procurement in excess of system capacities may result in loss of product through overstocking and expiration.

- In situations where the cost estimate for procurement exceeds the available funding, program managers should use the results of the quantification and requirements estimate to mobilize resources to fill the gap. Experience has shown that program managers can be effective in advocating for increased funding if a quantifiable gap in quantities and in funds can be demonstrated, and if the calculations are based on quality data, informed assumptions, and a systematic approach to quantification.
- If further resources are not available, an adjustment has to be made to the requirements estimation. The method for how this adjustment should be done will vary by country and by program. At the very least, this process will require program managers to make decisions on the priorities for HIV testing for various uses to determine the quantities to procure. In situations of non-full supply of HIV test kits, the budget reconciliation step typically involves setting priorities for the purposes (e.g., Blood Safety, VCT, PMTCT, SS, HCT), and priorities for other uses for the kits and for the reduction of quantities to be procured to fit available funds. The budget reconciliation step could also involve revisiting previous decisions regarding protocol. But regardless of which decisions are made when setting priorities, a basic standard to uphold is that test kits should be procured in the proper proportion to ensure that the protocol can be completed.
- In other situations, the purpose of the quantification may be to determine how many clients can be tested for a year, given a specific amount of funding available. In that case, the cost of testing a specific number of clients (e.g., cost per client or cost per 1,000 clients) can be quantified for and then matched against available funding to determine the total number of clients who could receive HIV testing within the year.

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

USING ProQ SOFTWARE FOR QUANTIFICATION AND PIPELINE SOFTWARE FOR PROCUREMENT PLANNING OF HIV TESTS

All the steps described in the guide correspond to standard quantification methodologies, but they are organized so that the ProQ¹ quantification software package can be used to perform all the calculations. Forecasting demand for HIV tests is complicated by the multiple purposes that HIV tests are used for, the varying methodologies that can be used to forecast demand, and the large number of brands of tests that might be available or that might be used in a program.

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

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

¹ For information about ProQ or to obtain a free copy of the software and the users manual, email info@deliver.com, visit www.deliverjsi.com, or send a letter to Publications Department, DELIVER, John Snow, Inc., 1616 N. Fort Myer Dr., 11th Floor, Arlington, VA 22209-3100 USA.

SUMMARY OF CHALLENGES AND LESSONS LEARNED IN QUANTIFICATION OF HIV TESTS

COMMON CHALLENGES

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

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

USEFUL LESSONS

The following lessons learned from the DELIVER experience in conducting HIV test quantifications in these countries have also been incorporated into the approach to quantification that has been presented in this guide.

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

ADDITIONAL CONSIDERATIONS

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

- All other technical factors being equal, preference in selection should be given to HIV tests that do not require cold storage, that have the longest shelf lives, and that are as self-contained with peripheral supplies as possible.
- The emphasis in procurement should be on developing supplier relationships that allow for frequent shipments of relatively small quantities of freshly manufactured kits. When possible, the purchasing contract should allow for accelerating or delaying the delivery of test kits to the program in response to the actual consumption of the test kits.
- The shipment schedule for the HIV test kits must reflect the lead time and shelf life for each product, as well as the current storage and distribution capacity of the logistics system. For example, tests with a short shelf life and cold chain storage requirements may have to be manufactured and shipped to a country at more frequent intervals than HIV test kits that have a longer shelf life and that can be stored at room

temperature. The in-country pipeline for those items would need to be shorter than for drugs and other supplies, and the test kits would need to be delivered to service delivery points more frequently.

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

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

QUESTIONS

BLOOD SAFETY

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

VOLUNTARY COUNSELING AND TESTING (VCT)

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

9. From where do the NGO and Mission sector VCT sites receive their HIV tests?
10. What brands and types of HIV tests are used at what levels in the program?]

PREVENTION OF MOTHER-TO-CHILD TRANSMISSION (PMTCT)

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

TESTING OF HIV-EXPOSED BABIES

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

HIV COUNSELING AND TESTING (HCT)

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

SENTINEL SURVEILLANCE

1. How many sentinel surveillance sites are there and of what type?
2. What is the sample size per sentinel surveillance site?
3. Where are sentinel surveillance site blood samples tested?
4. Is sentinel surveillance an ongoing, year-round activity, or is it for a limited time each year?
5. What brands and types of HIV tests are used for sentinel surveillance?

METHODOLOGIES

CONSUMPTION-BASED OR LOGISTICS METHODOLOGY

In this methodology, the forecast is based on stock consumption rates. This methodology is most useful in mature, stable testing programs that have a full supply of test kits and where reliable data are available. It is useful only in a system where prior consumption can be determined or at least extrapolated. One caution on using this methodology is that data on past consumption of HIV tests may not be predictive of future use because past testing was often undertaken on a pilot or small-scale basis, often by nongovernmental organizations. Also, if the program has experienced frequent stockouts of test kits, the consumption figures might be understated relative to what consumption would have been if the test kits had been available in full supply.

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

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

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

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

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

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

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

Compare the consumption of tests in question 1 to the consumption resulting from the calculations in questions 3–6, and select the figure you wish to use for this quantification. Generally, you should select the consumption figure on the basis of what you perceive to be the most reliable data.

Question 7—Discuss with key informants the expected rate of change (increase or decrease) in use of HIV tests for the year you are quantifying. Take into account economic, political, and programmatic factors such as information campaigns, expansion of service networks, funding shortfalls, etc., that could raise or lower demand for HIV testing for the forecast period.

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

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

$$\begin{aligned} & \text{(Estimated consumption for the year)} \\ & \quad \div \text{(number of days the facilities had tests in stock)} \\ & \quad \times \text{(number of days the facilities were stocked out of tests)} \end{aligned} = \text{estimated number of tests} \\ & \quad \text{that would have been} \\ & \quad \text{consumed during periods} \\ & \quad \text{of the stockout.} \end{aligned}$$

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

MORBIDITY-BASED (DEMOGRAPHIC) METHODOLOGY

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

BLOOD SAFETY

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

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

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

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

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

Question 6—Determine from published guidelines for blood safety, discussions with key informants, and field observations, which of the HIV testing protocols are used for blood safety.

If testing protocol S3 is in use, which is three tests conducted serially, demand for HIV tests would be calculated as follows:

(Population of the service area) × (% of population donating blood) × (times per year that a donor donates blood)	=	estimated units of blood to be collected
	=	demand for HIV screening tests.
(Units of blood to be collected) × (blood donor HIV prevalence rate)	=	demand for HIV screening tests.
(Demand for HIV confirmatory tests) × (discordance rate between HIV screening and confirmatory tests)	=	demand for HIV tie- breaking tests.

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

VOLUNTARY COUNSELING AND TESTING (VCT)

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

(Population of service area) × (% of population likely to come for VCT) × (% of counseled clients likely to accept testing)	=	demand for HIV screening tests.
(Demand for HIV screening tests) × (HIV prevalence rate among VCT clients)	=	demand for HIV confirmatory tests.
(Demand for HIV confirmatory tests) × (discordance rate between screening and confirmatory tests)	=	demand for HIV tie-breaking tests.

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

PREVENTION OF MOTHER-TO-CHILD TRANSMISSION (PMTCT)

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

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

$$\begin{aligned} & \text{(Demand for HIV confirmatory tests)} \\ & \times \text{(discordance rate between screening and confirmatory tests)} \end{aligned} = \begin{aligned} & \text{demand for HIV} \\ & \text{tie-breaking tests.} \end{aligned}$$

TESTING OF HIV-EXPOSED BABIES

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

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

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

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

HIV COUNSELING AND TESTING (HCT)

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

$$\begin{aligned}
 & \text{(Population of clinic service areas)} \\
 & \times (\% \text{ if population is likely to access program clinics}) \\
 & \times (\% \text{ of population accessing program clinics who will show signs} \\
 & \quad \text{and symptoms of AIDS}) \\
 & \text{(Demand for HIV screening tests for HCT)} \times (\text{HIV prevalence rate} \\
 & \quad \text{among clinic patients}) \\
 & \text{(Demand for HIV confirmatory tests for HCT)} \\
 & \times (\text{discordance rate between screening and confirmatory tests})
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 \end{array}$$

MORBIDITY-BASED (SERVICE STATISTICS) METHODOLOGY

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

BLOOD SAFETY

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

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

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

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

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

$$\begin{aligned}
 & \text{(Units of blood collected in the past year)} \\
 & \times (1 + \text{expected rate of change in blood collection}) \\
 & \text{(Demand for HIV screening tests)} \\
 & \times (\text{HIV prevalence rate among blood donors}) \\
 & \text{(Demand for HIV confirmatory tests for blood safety)} \\
 & \times (\text{discordance rate between screening and confirmatory} \\
 & \quad \text{tests})
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 \text{units of blood to be collected in} \\
 \text{the forecast year} \\
 \text{demand for HIV screening tests.} \\
 \\
 \text{demand for HIV confirmatory} \\
 \text{tests for blood safety.} \\
 \\
 \text{demand for HIV tie-breaking} \\
 \text{tests for blood safety.}
 \end{array}$$

VOLUNTARY COUNSELING AND TESTING

Under protocol S3, the tests required for VCT would be calculated as follows:

$$\begin{aligned} & \text{(VCT clients tested in the past year)} & & \text{demand for HIV screening tests} \\ & \times \text{(1 + expected rate of change in VCT testing)} & = & \text{for VCT in the year for which} \\ & & & \text{you are quantifying.} \\ & \text{(Demand for screening tests for VCT)} & = & \text{demand for HIV confirmatory} \\ & \times \text{(HIV prevalence rate among VCT clients)} & = & \text{tests for VCT.} \\ & \text{(Demand for HIV confirmatory tests for VCT)} & = & \text{demand for HIV tie-breaking test} \\ & \times \text{(Discordance rate between screening and confirmatory tests)} & = & \text{for VCT.} \end{aligned}$$

PREVENTION OF MOTHER-TO-CHILD TRANSMISSION

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

$$\begin{aligned} & \text{(Number of pregnant women who were tested for HIV in the past} & & \text{demand for HIV screening tests} \\ & \text{year in the PMTCT Program)} & = & \text{for PMTCT in the year for} \\ & \times \text{(1 + expected rate of change in PMTCT testing)} & & \text{which you are quantifying.} \\ & \text{(Demand for HIV screening tests for PMTCT)} & = & \text{demand for HIV confirmatory} \\ & \times \text{(HIV prevalence rate among PMTCT clients)} & = & \text{tests for PMTCT.} \\ & \text{(Demand for HIV confirmatory tests for PMTCT)} & & \\ & \times \text{(Discordance rate between HIV screening and HIV} & = & \text{demand for HIV tie-breaker} \\ & \text{confirmatory tests)} & & \text{tests for PMTCT.} \end{aligned}$$

TESTING OF HIV-EXPOSED BABIES AND OTHER USES

Under testing protocol S3 the tests required for testing of HIV-exposed babies and for other uses would be calculated in the same manner as for VCT and PMTCT.

TARGET METHODOLOGY

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

$$\begin{aligned} & \text{The number of clients or blood samples targeted} & = & \text{demand for HIV screening tests.} \\ & \text{(Demand for HIV screening tests)} & = & \text{demand for HIV} \\ & \times \text{(HIV prevalence rate for the target group)} & = & \text{confirmatory tests.} \\ & \text{(Demand for HIV confirmatory tests)} & & \\ & \times \text{(discordance rate between screening and confirmatory} & = & \text{demand for HIV tie-breaking tests.} \\ & \text{tests)} & & \end{aligned}$$

For sentinel surveillance, the World Health Organization's protocol recommends only one test, so no confirmatory test is used. Some number or percentage of screening samples is randomly selected for quality control testing. If these quality control test results differ from the screening test results, further tests may be used for validation.

APPENDIX C

INFORMATION REQUIRED TO FORECAST DEMAND

TABLE I. DATA REQUIRED TO FORECAST ADJUSTED DEMAND FOR HIV TESTS FOR BLOOD SAFETY

DEMAND			
Logistics	Demographic/Morbidity	Service Statistics	Target
<ol style="list-style-type: none"> How many of each brand of tests were consumed the past for blood safety? What is the lowest level of the system having relatively complete data? For this level of the logistic system, what was the beginning inventory of each brand of test at the start of the year? For this level of the logistic system, what were the receipts for each brand of test for the year? For this level of the logistic system, what were the expiries, losses, and adjustments for each brand of test for the year? For this level of the logistic system, what was the ending inventory for the year? What is the expected rate of change of HIV test consumption for blood safety for the year for which you are quantifying? 	<ol style="list-style-type: none"> What is the population of the catchment area covered by this blood safety program? What percentage of people in this population will donate blood? On average, how many times does a blood donor donate per year? What is the HIV prevalence rate among blood donors? What is the average discordance rate between the screening and confirmatory tests? What is the HIV testing protocol for blood safety? 	<ol style="list-style-type: none"> How many blood units were collected during the past year? How many blood units were transfused during the past year? What percentage of blood units collected during the past year was discarded (include blood units discarded for testing positive for pathogens, expiry, and other reasons)? What is the expected rate of change in blood collection in the year for which you are quantifying? What is the HIV prevalence rate among blood donors? What is the average discordance rate between the screening and confirmatory tests? What is the HIV testing protocol for blood safety? 	<ol style="list-style-type: none"> What is the targeted number of blood units to be collected in the year for which you are quantifying? What is the HIV prevalence rate among blood donors? What is the average discordance rate between the screening and confirmatory tests? What is the HIV testing protocol for blood safety?
	Quality Control and Wastage Factors		
	<ol style="list-style-type: none"> What percentage of each brand of test will be used for quality control purposes? What percentage of each brand of test will be wasted through expiry, faulty product, etc.? 		
Service Capacity			
<ol style="list-style-type: none"> For blood safety, what is the total number of technicians conducting HIV tests? How many days a year, on average, will a technician conduct HIV tests for blood safety? On average, how many HIV tests for blood safety will a technician conduct per day? If reliable service capacity data are not available, discuss with key informants the testing capacity for blood safety. Using this information, determine the maximum number of tests that can be conducted for purposes of blood safety during the year for which you are quantifying. 			
If an ELISA/Blot is picked for the test selection—			
<ol style="list-style-type: none"> What is the yearly laboratory machine capacity for conducting the HIV test indicated in the product selection? 			

TABLE 2. DATA REQUIRED TO FORECAST ADJUSTED DEMAND FOR HIV TESTS FOR VOLUNTARY COUNSELING AND TESTING (VCT)

DEMAND			
Logistics	Demographic/ Morbidity	Service Statistics	Target
<ol style="list-style-type: none"> How many of each brand of tests were consumed for VCT in the past year? What is the lowest level of the system having relatively complete data? For this level of the logistic system, what was the beginning inventory for each brand of test at the start of the year? For this level of the logistic system, what were the receipts for each brand of test for the year? For this level of the logistic system, what were the expiries, losses, and adjustments for each brand of test for the year? For this level of the logistic system, what was the ending inventory for each brand of test for the year? What is the expected rate of change of HIV test consumption for VCT in the year you are quantifying? 	<ol style="list-style-type: none"> What is the total population of the catchment areas served by VCT sites? What percentage of the population in the catchment areas served by VCT sites is likely to come for counseling? What percentage of counseled clients is likely to request an HIV test? What is the HIV prevalence rate of VCT clients requesting an HIV test? What is the average discordance rate between the screening and confirmatory tests? What is the testing protocol for VCT? 	<ol style="list-style-type: none"> For VCT, how many clients were tested during the past year? What is the HIV prevalence rate among the tested clients? What is the expected rate of change for VCT? What is the average discordance rate between the screening and confirmatory tests? What is the testing protocol for VCT? 	<ol style="list-style-type: none"> What is the targeted number of VCT clients to be tested in the year you are quantifying? What is the HIV prevalence rate among VCT clients? What is the average discordance rate between the screening and confirmatory tests? What is the testing protocol for VCT?
Quality Control and Wastage Factors			
<ol style="list-style-type: none"> What percentage of each brand of test will be used for quality control purposes? What percentage of each brand of test will be wasted through expiry, faulty product, etc.? 			
Service Capacity			
<ol style="list-style-type: none"> For the VCT program, what is the total number of counselors? How many days a year, on average, will a counselor do VCT? Do counselors conduct HIV tests? YES <input type="checkbox"/> NO <input type="checkbox"/> <p>If YES, proceed to question #4A. If NO, proceed to question #4B.</p>			

4A. On average, how many VCT clients per day will a counselor counsel if this same counselor is also conducting the tests?

5A. What percentage of counseled clients is likely to request HIV testing?

– OR –

6A. If reliable service capacity data are not available, discuss with key informants the counseling and testing capacity for VCT. Using this information, determine the maximum number of clients who can be tested in the VCT program during the year you are quantifying.

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

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

6B. For the VCT program, what is the total number of technicians conducting HIV tests?

7B. How many days a year, on average, will a technician conduct HIV tests for VCT?

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

– OR –

9B. If reliable service capacity data is not available, discuss with key informants the testing capacity for VCT. Using this information, determine maximum number of clients who can be tested in the VCT program during the year you are quantifying.

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

10B. What is the yearly laboratory machine capacity for conducting the HIV test indicated in the product selection for VCT?

TABLE 3. DATA REQUIRED TO FORECAST ADJUSTED DEMAND FOR HIV TESTS FOR PREVENTION OF MOTHER-TO-CHILD TRANSMISSION (PMTCT)

DEMAND			
Logistics	Demographic/ Morbidity	Service Statistics	Target
<ol style="list-style-type: none"> How many of each brand of tests were consumed during the past year for PMTCT? What is the lowest level of the system having relatively complete data? For this level of the logistic system, what was the beginning inventory for each brand of test at the start of the year? For this level of the logistic system, what were the receipts for each brand of test for the year? For this level of the logistic system, what were the expiries, losses, and adjustments for each brand of test for the year? For this level of the logistic system, what was the ending inventory for each brand of test for the year? What is the expected rate of change of HIV test consumption for PMTCT? 	<ol style="list-style-type: none"> How many women of reproductive age live in the catchment area of ANC sites offering PMTCT? What is the pregnancy rate in the catchment area? What percentage of pregnant women in the catchment areas will make at least one ANC visit? What percentage of these ANC clients is likely to request counseling for HIV? What percentage of ANC clients counseled is likely to request an HIV test? What is the HIV prevalence rate among PMTCT clients? What is the average discordance rate between the screening and confirmatory tests? What is the testing protocol for PMTCT? 	<ol style="list-style-type: none"> How many pregnant women were tested for HIV in sites offering PMTCT in the past year? What is the HIV prevalence rate among pregnant women tested at PMTCT sites in the past year? What is the average discordance rate between the screening and confirmatory tests? What is the expected rate of change for PMTCT testing? What is the testing protocol for PMTCT? 	<ol style="list-style-type: none"> What is the targeted number of clients to be tested for PMTCT in the year for which you are quantifying? What is the HIV prevalence rate among PMTCT clients? What is the average discordance rate between the screening and confirmatory tests? What is the testing protocol for PMTCT?
Quality Control and Wastage Factors			
<ol style="list-style-type: none"> What percentage of each brand of test will be used for quality control purposes? What percentage of each brand of test will be wasted through expiry, faulty product, etc.? 			
Service Capacity			
<ol style="list-style-type: none"> For the PMTCT program, what is the total number of counselors? How many days a year, on average, will a counselor do PMTCT? Do counselors themselves conduct HIV tests? YES <input type="checkbox"/> NO <input type="checkbox"/> If YES, proceed to question #4A. If NO, proceed to question #4B. <p>(Continue with question 4A or 4B on the next page)</p>			

<p>4A. On average, how many PMTCT clients per day will a counselor counsel if this same counselor is also conducting the tests?</p> <p>5A. What percentage of counseled clients is likely to request HIV testing?</p> <p style="text-align: center;">– OR –</p> <p>6A. If reliable service capacity data is not available, discuss with key informants the counseling and testing capacity for PMTCT. Using this information, determine the maximum number of clients who can be tested in the program for the testing of HIV-exposed babies during the year you are quantifying.</p>	<p>4B. On average, how many PMTCT clients per day will a counselor counsel?</p> <p>5B. What percentage of counseled clients is likely to request HIV testing?</p> <p>6B. For the PMTCT program, what is the total number of technicians conducting HIV tests?</p> <p>7B. How many days a year, on average, will a technician conduct HIV tests for PMTCT?</p> <p>8B. On average, how many HIV tests for PMTCT will a technician conduct per day?</p> <p style="text-align: center;">– OR –</p> <p>9B. If reliable service capacity data is not available, discuss with key informants the testing capacity for PMTCT. Using this information, determine the maximum number of clients who can be tested in the program for the testing of HIV-exposed babies during the year you are quantifying.</p> <p>If an ELISA/Blot is picked for the test kit selection—</p> <p>10B. What is the yearly laboratory machine capacity for conducting the HIV test indicated in the product selection for PMTCT?</p>
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TABLE 4. DATA REQUIRED TO FORECAST ADJUSTED DEMAND FOR HIV TESTS FOR TESTING HIV-EXPOSED BABIES

DEMAND			
Logistics	Demographic/ Morbidity	Service Statistics	Target
<ol style="list-style-type: none"> How many of each brand of tests were consumed during the past year³ for testing HIV-exposed babies? What is the lowest level of the system having relatively complete data? For this level of the logistic system, what was the beginning inventory for each brand of test at the start of the year?⁴ For this level of the logistic system, what were the receipts for each brand of test for the year? For this level of the logistic system, what were the expiries, losses, and adjustments for each brand of test for the year? For this level of the logistic system, what was the ending inventory for each brand of test for the year? What is the expected rate of change of HIV test consumption for testing HIV-exposed babies? 	<ol style="list-style-type: none"> What percentage of babies of HIV-positive PMTCT clients will be brought for HIV testing at age 9 months? What is the percentage of HIV-exposed babies who test HIV-negative at age 9 months? What percentage of HIV-negative babies at age 9 months will still be breastfeeding? What percentage of HIV-negative babies still breastfeeding at 9 months will be brought for retesting 3 months after being weaned from breast milk? What percentage of HIV-exposed babies test HIV-positive at age 9 months? What percentage of HIV-positive babies at age 9 months will be brought for retesting at age 18 months? What percentage of HIV-negative babies at age 18 months will still be breastfeeding? What percentage of HIV-negative babies still breastfeeding at 18 months will be brought for retesting 3 months after being weaned from breast milk? What is the average discordance rate between the screening and confirmatory tests? What is the testing protocol for testing HIV-exposed babies? 	<ol style="list-style-type: none"> How many HIV-exposed babies were tested in the ANC sites offering PMTCT during the previous year?³ What was the HIV prevalence rate among HIV-exposed babies tested at ANC clinics? What is the average discordance rate between the screening and confirmatory tests? What is the expected rate of change for testing HIV-exposed babies? What is the testing protocol for testing HIV-exposed babies? 	<ol style="list-style-type: none"> What is the targeted number of HIV-exposed babies to be tested in the year you are quantifying? What is the HIV prevalence rate among HIV-exposed babies? What is the average discordance rate between the screening and confirmatory tests? What is the testing protocol for testing HIV-exposed babies?

	Quality Control and Wastage Factors
	<p>1. What percentage of each brand of test will be used for quality control purposes?</p> <p>2. What percentage of each brand of test will be wasted through expiry, faulty product, etc.?</p>

Service Capacity

1. In the program for testing of HIV-exposed babies, what is the total number of counselors?
2. How many days a year, on average, will a counselor counsel caregivers of HIV-exposed babies?
3. Do counselors conduct HIV tests? YES NO

If YES, proceed to question #4A. If NO, proceed to question #4B.

<p>4A. On average, how many caregivers of HIV-exposed babies will a counselor counsel per day if this same counselor is also conducting the tests?</p> <p>5A. If reliable service capacity data are not available, discuss with key informants the counseling and testing capacity for testing HIV-exposed babies. Using this information, determine the maximum number of clients who can be tested in the PMTCT program during the year you are quantifying.</p> <p>4B. On average, how many caregivers of HIV-exposed babies will a counselor counsel per day if the counselors are not conducting the tests?</p>	<p>5B. For the testing of HIV-exposed babies program, what is the total number of technicians conducting HIV tests?</p> <p>6B. How many days a year, on average, will a technician conduct HIV tests for the testing of HIV-exposed babies program?</p> <p>7B. On average, how many HIV tests for the testing of HIV-exposed babies will a technician conduct per day?</p> <p>8B. If reliable service capacity data are not available, discuss with key informants the testing capacity for the testing of HIV-exposed babies program. Using this information, determine the maximum number of clients who can be tested in the PMTCT program during the year you are quantifying.</p> <p>If an ELISA/Blot is picked for the test kit selection—</p> <p>9B. What is the yearly laboratory machine capacity for conducting the HIV test indicated in the product selection for the testing of HIV-exposed babies program?</p>
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TABLE 5. DATA REQUIRED TO FORECAST ADJUSTED DEMAND FOR HIV TESTS FOR SENTINEL SURVEILLANCE

DEMAND			
Logistics	Demographic/ Morbidity	Service Statistics	Target
N/A	N/A	N/A	<ol style="list-style-type: none"> 1. How many people will be tested for HIV in the sentinel surveillance program in the year you are quantifying? 2. How many or what percentage of the screened specimens will be tested for quality control? 3. What is the average discordance rate between the screening and quality control tests, or what percentage or number of the quality control tests will require validation testing? 4. What is the testing protocol for sentinel surveillance?
Quality Control and Wastage Factors			
<ol style="list-style-type: none"> 1. What percentage of each brand of test will be used for quality control purposes? 2. What percentage of each brand of test will be wasted through expiry, faulty product, etc.? 			
Service Capacity			
<ol style="list-style-type: none"> 1. For sentinel surveillance, what is the total number of technicians conducting HIV tests? 2. How many days a year, on average, will a technician conduct HIV tests for sentinel surveillance? 3. On average, how many HIV tests for sentinel surveillance will a technician conduct per day? <p style="text-align: center;">– OR –</p> <ol style="list-style-type: none"> 4. If reliable service capacity data is not available, discuss with key informants the testing capacity for sentinel surveillance. Using this information, determine the maximum number of tests that can be conducted for sentinel surveillance during the year you are quantifying. <p>If an ELISA/Blot is picked for the test kit selection—</p> <ol style="list-style-type: none"> 5. What is the yearly laboratory machine capacity for conducting the HIV test indicated in the product selection? 			

TABLE 6. DATA REQUIRED TO FORECAST ADJUSTED DEMAND FOR HIV TESTS FOR HIV COUNSELING AND TESTING (HCT)

DEMAND			
Logistics	Demographic/ Morbidity	Service Statistics	Target
<ol style="list-style-type: none"> How many of each brand of tests were consumed in the past year³ for HCT? What is the lowest level of the system having relatively complete data? For this level of the logistic system, what was the beginning inventory for each brand of test at the start of the year? For this level of the logistic system, what were the receipts for each brand of test for the year? For this level of the logistic system, what were the expiries, losses, and adjustments for each brand of test for the year? For this level of the logistic system, what was the ending inventory for each brand of test for the year? What is the expected rate of change of HIV test consumption for HCT? 	<ol style="list-style-type: none"> What is the population of the catchment areas of health facilities receiving HIV tests under this program? What percentage of the population in the catchment area will access medical facilities this year? What percentage of individuals accessing medical facilities is tested for HIV? In the catchment areas, what is the AIDS prevalence of the population accessing medical facilities? What is the average discordance rate between the screening and confirmatory tests? What is the testing protocol for HCT? 	<ol style="list-style-type: none"> How many HIV tests were conducted in clinical settings during the past year³ for diagnostic testing? What is the expected rate of change in HIV testing through HCT in the year you are quantifying? How many of the HIV tests conducted in the past year through HCT testing were HIV-positive? What is the average discordance rate between the screening and confirmatory tests? What is the testing protocol for HCT? 	<ol style="list-style-type: none"> What is the anticipated number of clients to be tested for HIV through HCT in the year you are quantifying? What is the HIV prevalence rate of clients tested for HIV through HCT? What is the average discordance rate between the screening and confirmatory tests? What is the testing protocol for HCT?
Quality Control and Wastage Factors			
<ol style="list-style-type: none"> What percentage of each brand of test will be used for quality control purposes? What percentage of each brand of test will be wasted through expiry, faulty product, etc.? 			
Service Capacity			
<ol style="list-style-type: none"> For HCT, what is the total number of technicians conducting HIV tests? How many days a year, on average, will a technician conduct HIV tests for HCT? On average, how many HIV tests for HCT will a technician conduct per day? <p style="text-align: center;">– OR –</p> <ol style="list-style-type: none"> If reliable service capacity data is not available, discuss with key informants the testing capacity for HCT. Using this information, determine the maximum number of tests that can be conducted for HCT during the year you are quantifying. <p>If an ELISA/Blot is picked for the test kit selection—</p> <ol style="list-style-type: none"> What is the yearly laboratory machine capacity for conducting the HIV test indicated in the product selection? 			

TABLE 7. DATA REQUIRED TO FORECAST ADJUSTED DEMAND FOR HIV TESTS FOR OTHER USES (INCLUDING TRAINING AND RESEARCH)

DEMAND			
Logistics	Demographic/ Morbidity	Service Statistics	Target
<ol style="list-style-type: none"> 1. How many of each brand of tests were consumed during the past year³ for the other uses you are quantifying? 2. What is the lowest level of the system having relatively complete data? 3. For this level of the logistic system, what was the beginning inventory for each brand of test at the start of the year? 4. For this level of the logistic system, what were the receipts for each brand of test for the year? 5. For this level of the logistic system, what were the losses and adjustments for each brand of test for the year? 6. For this level of the logistic system, what was the ending inventory for each brand of test for the year? 7. What is the expected rate of change of HIV test consumption for other uses? 	N/A	<ol style="list-style-type: none"> 1. How many clients were tested for HIV in the past year³ for the other uses you are quantifying? 2. What is the percentage expected rate of change in testing for the other uses you are quantifying? 3. What is the HIV prevalence rate for clients tested for the other uses you are quantifying? 4. What is the average discordance rate between the screening and confirmatory tests? 5. What is the testing protocol for the other uses you are quantifying? 	<ol style="list-style-type: none"> 1. How many clients are targeted to be tested for HIV for the other use(s) you are quantifying? 2. What is the HIV prevalence rate for clients tested for the other use(s) you are quantifying? 3. What is the average discordance rate between the screening and confirmatory tests? 4. What is the testing protocol for the other use(s) you are quantifying?
Quality Control and Wastage Factors			
<ol style="list-style-type: none"> 1. What percentage of each brand of test will be used for quality control purposes? 2. What percentage of each brand of test will be wasted through expiry, faulty product, etc.? 			

Service Capacity

1. For the other use(s) you are quantifying, what is the total number of technicians conducting HIV tests?
2. How many days a year, on average, will a technician conduct HIV tests for the other use(s) you are quantifying?
3. On average, how many HIV tests for the other use(s) you are quantifying will a technician conduct per day?

– OR –

4. If reliable service capacity data are not available, discuss with key informants the testing capacity for the other uses you are quantifying. Using this information, determine the maximum number of tests that can be conducted for the uses during the year you are quantifying.

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

5. What is the yearly laboratory machine capacity for conducting the HIV test indicated in the product selection?
-

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