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GUIDE FOR QUANTIFYING LABORATORY SUPPLIES

July 2008

This publication was produced for review by the U.S. Agency for International Development. It was prepared by the USAID | DELIVER PROJECT, Task Order 1.

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The USAID | DELIVER PROJECT, Task Order 1, is funded by the U.S. Agency for International Development under contract no. GPO-I-01-06-00007-00, beginning September 29, 2006. HIV-related activities of Task Order 1 are supported by the President's Emergency Plan for AIDS Relief. Task Order 1 is implemented by John Snow, Inc., in collaboration with PATH, Crown Agents Consultancy, Inc., Abt Associates, Fuel Logistics Group (Pty) Ltd., UPS Supply Chain Solutions, The Manoff Group, and 3i Infotech. The project improves essential health commodity supply chains by strengthening logistics management information systems, streamlining distribution systems, identifying financial resources for procurement and supply chain operations, and enhancing forecasting and procurement planning. The project also encourages policymakers and donors to support logistics as a critical factor in the overall success of their health care mandates.

Recommended Citation
Diallo, Abdourahmane, Claudia Allers, Yasmin Chandani, Wendy Nicodemus, Colleen McLaughlin, Lea Teclemariam, and Ronald Brown. 2008. *Guide for Quantifying Laboratory Supplies*. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 1.

Abstract
Laboratory commodities are used to provide preventive and care services that support public health programs, such as human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS), tuberculosis, and malaria. Without adequate laboratory supplies or an effective supply chain to deliver the commodities to facilities on a continuous basis, investments in provision of these services will not be maximized. The specific characteristics and quantities of laboratory commodities to be handled pose a particular challenge to managing the supply chain. Quantification of health commodities is a process that includes estimating the quantities and the cost of products required to meet customer demand and to fill the pipeline with adequate stock levels, taking into account service delivery capacity, supply pipeline requirements, and resources available for procurement. The primary focus and purpose of this guide is to describe the process and the methodologies used for quantifying laboratory commodities.

Cover photo: Microscopes and a water bath in a lab in Zambia. Photo taken by Carmit Keddem.

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ACRONYMS

ABC	analysis for classification using A, B, C
AFB	acid-fast bacilli
AIDS	acquired immunodeficiency syndrome
ALT	alanine aminotransferase
ART	antiretroviral therapy
BMS	Buffalo Medical Specialties
CBC	complete blood count
CD4/CD8	cluster of differentiation (ratio of CD4 cells to CD8 cells)
CDC	Centers for Disease Control and Prevention
CSF	cerebrospinal fluid
CO_2	carbon dioxide
EDTA	ethylenediaminetetraacetic acid
ELISA	enzyme-linked immunosorbent assay
g	gram
GPR	general-purpose reagent
Hb	hemoglobin
HIV	human immunodeficiency virus
HVS	high vaginal swab
JSI	John Snow, Inc.
KOH	potassium hydroxide
LMIS	logistics management information system
mL	milliliter
MOH	Ministry of Health
NGO	nongovernmental organization
p24	protein 24 antigen
PEPFAR	President's Emergency Plan for AIDS Relief
pH	potential hydrogen (measure of acidity)
PMTCT	preventing mother-to-child transmission
RNA	ribonucleic acid

RPR	rapid plasma reagin
SGOT	serum glutamic oxaloacetic transaminase (AST)
SGPT	serum glutamic pyruvic transaminase (ALT)
SOH	stock on hand
SOP	standard operating procedure
STG	standard treatment guideline
STI	sexually transmitted infection
SS	sentinel surveillance
TB	tuberculosis
TPHA	treponema pallidum hemagglutination assay
USAID	U.S. Agency for International Development
VCT	voluntary counseling and testing
VDRL	Venereal Disease Research Laboratory
VEN	vital, essential, nonessential
ZN	Ziehl-Neelsen

ACKNOWLEDGMENTS

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

The U.S. Agency for International Development (USAID) contracts funded the technical assistance, in-country projects, and research that produced the experience and lessons contained in the *Resources*. We are deeply grateful to the team of professionals in the Commodity Security and Logistics Division in the Office of Population and Reproductive Health of the USAID Global Health Bureau's Center for Population, Health, and Nutrition for their encouragement and advice, and for their commitment to improving HIV & AIDS laboratory and public health programs through logistics.

Numerous people helped write the documents that constitute the *Resources*. Sincere thanks go to the extended core team of dedicated technical staff from the field and from the project office in Arlington, VA, who developed and wrote the multiple components of this CD. The lessons drawn from the experience of the USAID | DELIVER PROJECT and its predecessor project, the John Snow, Inc./DELIVER project, in managing HIV & AIDS and laboratory supply chains would not have been possible without these valuable contributions.

PREFACE

It has been recently recognized that the quality of HIV & AIDS, tuberculosis (TB), and malaria programs is jeopardized by the lack of attention given to the key supportive components, such as laboratory services. Further exacerbating the quality of those programs is the fact that weak health commodity supply chains have failed to ensure a reliable supply of the products at service delivery sites at a time of rapid service expansion, such as in HIV & AIDS programs.

A significant number of public-sector programs in resource-poor countries urgently need enhanced capacity in quantification, financing, procurement, and delivery of laboratory commodities. Hence, global efforts to coordinate quantification, financing, and procurement are critical and must complement country-based initiatives.

Laboratory commodities are used in the provision of preventive and care services supporting public health programs. Without adequate laboratory supplies, or without an effective supply chain to deliver the commodities to facilities on a continuous basis, investments in provision of those services will not be maximized.

The specific characteristics and the quantities of laboratory commodities to be handled pose particular challenges for managing the supply chain. The management of laboratory commodities is extensively discussed in the manual *Guidelines for Managing the Laboratory Supply Chain* (DELIVER 2006c). This guide for quantifying laboratory supplies focuses on describing the process and the methodologies used for quantifying laboratory commodities.

This guide 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 laboratory commodities in countries such as Ghana, Kenya, and Uganda. DELIVER's experience indicates that two of the most critical supply chain interventions regarding laboratory commodities at this time are as follows:

- Establish robust data collection and reporting systems to improve the availability and quality of data on laboratory commodities.
- Build capacity in quantification of laboratory commodity 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 laboratory commodities 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, and as management information systems improve to enable more evidence-based quantifications. Therefore, this guide is a work in progress that will be reviewed and updated over time to reflect the growing body of knowledge and best practices in supply chain management for laboratory commodities.

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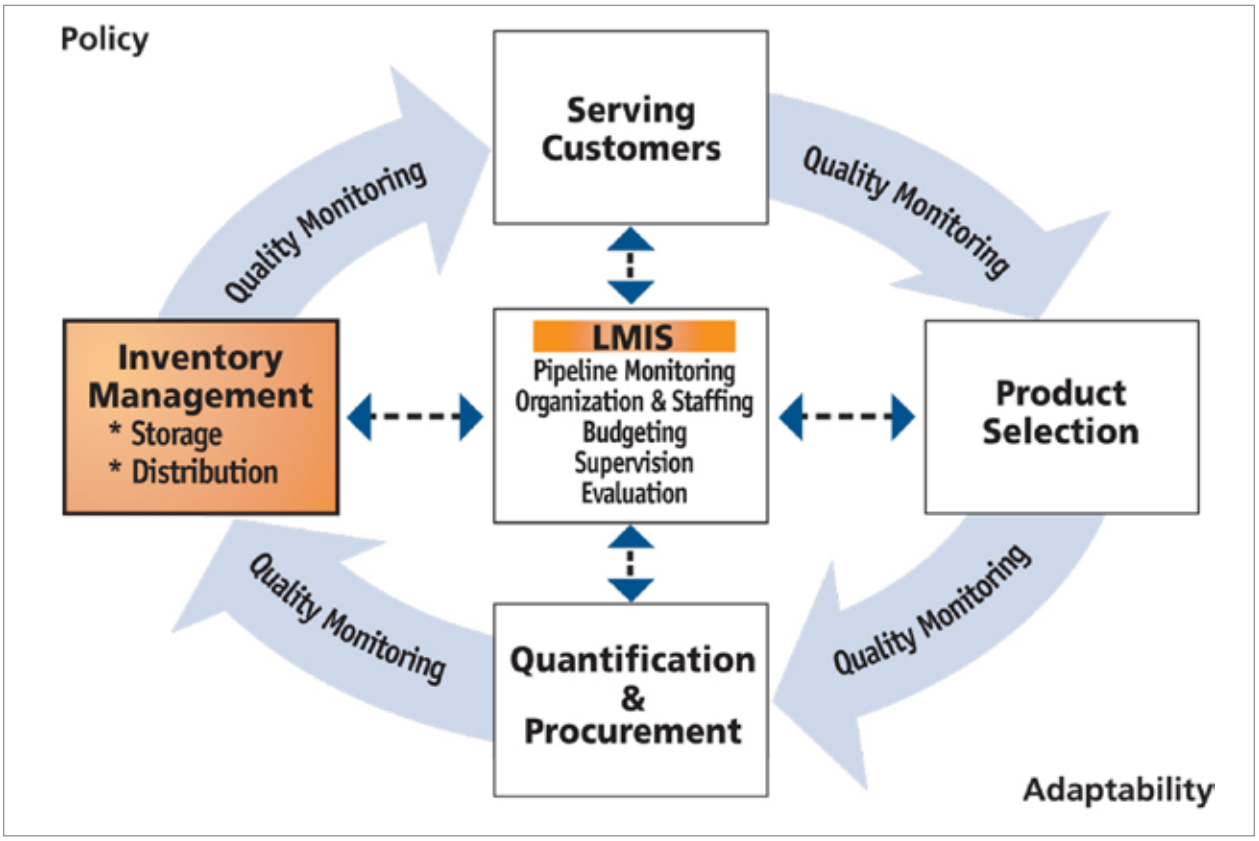
INTRODUCTION TO QUANTIFICATION

The approach to quantification originally developed by the John Snow, Inc./DELIVER project highlights the role and importance of quantification in improving supply chain management of health commodities. As depicted in Figure 1 below, quantification is a critical supply chain activity that links information on services and commodities from the facility level with program policies and plans at the national level, which are then used to inform higher-level decision making on the financing and procurement of commodities. In addition, the results of quantification should serve as an advocacy tool for maximizing the use of available resources, mobilizing additional resources when needed, and informing manufacturer production decisions.

Figure 1. The Logistics Cycle



Applying the quantification principles and following the steps in the quantification process described below during a national quantification exercise with in-country stakeholders and counterparts has proven successful in building local capacity in quantification and the use of available software tools, which has helped to improve the accuracy and usefulness of future quantifications.

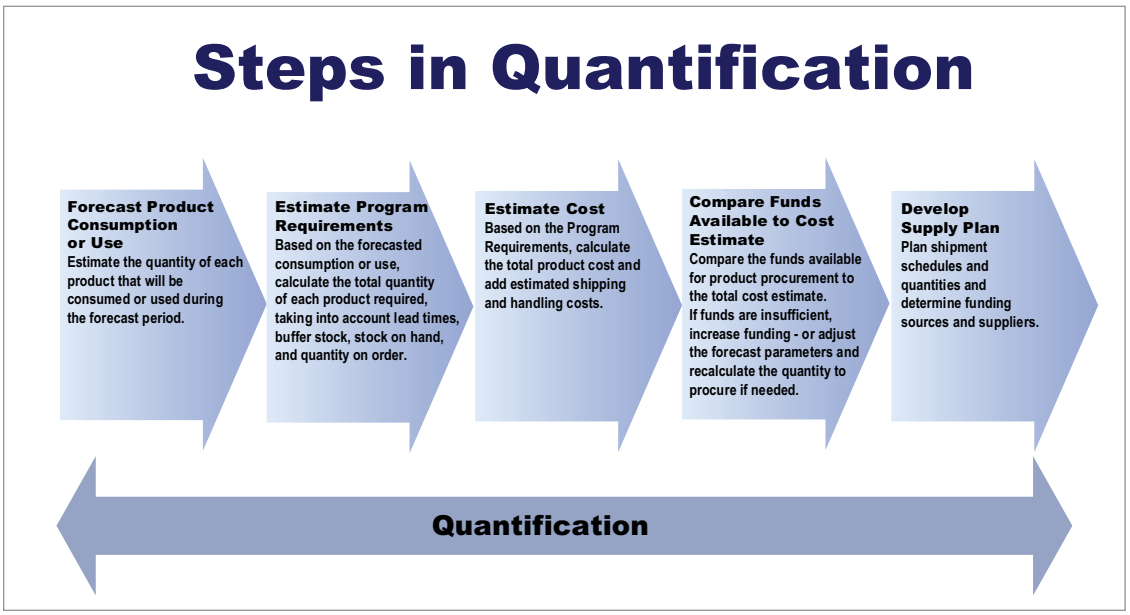
The key principles that guide the quantification process are as follows:

- Engage in a consultative and participatory process with a broad range of stakeholders, including program managers, government officials, donors, implementing partners, commodity managers, and service providers (clinicians, pharmacists, counselors, nurses, laboratory technicians)
- Use the quantification exercise to address policy and technical issues
- Facilitate a consensus-building approach to agree on the forecasting assumptions
- Use the results of the quantification as an advocacy tool for mobilization of needed resources

STEPS IN QUANTIFICATION

The specific steps in quantification are summarized in the diagram below, including the steps in which the different software tools are used.

Figure 2. Steps in Quantification



This is the overarching view of the quantification process which (moving from left to right) includes the steps of forecasting product consumption, estimating the total program requirements, estimating total commodity costs, reconciling costs with available funding, and supply planning as integral activities within the whole quantification process. This diagram also illustrates the points in the quantification process in which the available software tools can be used for forecasting, estimating the total program requirements and costs, and for supply planning.

FORECASTING PRODUCT CONSUMPTION

Forecasting product consumption means estimating the quantity of a product (e.g., drugs to be dispensed, HIV tests or laboratory reagents to be used) that will be consumed or used during a future period.

For health commodities, the basis of the forecast—such as the number of people to be served or the number of cases or episodes of a health condition to be treated—may need to be adjusted:

1) to reflect 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;
2) to take into account the program's service capacity according to the volume of services that can realistically be provided, given the existing infrastructure, staff availability and staff skills, and customer/patient/client access to services.

ESTIMATING PROGRAM REQUIREMENTS

Estimating the program requirements consists of determining the quantity of each product needed to meet the forecasted consumption and ensuring that the in-country supply pipeline has adequate stock levels to maintain continuous supply to service delivery points. The estimate of the total program requirements for the forecast period is determined by calculating the additional quantities of product needed to cover procurement and supplier lead times and buffer stocks, and then subtracting the quantity of each product already in stock in the country (stock on hand) and any quantities that may already have been ordered but have not yet been received (quantity on order). In some cases, the program requirements may need to be reduced and shipment delivery schedules adjusted to accommodate constraints in the storage and distribution capacity of the logistics system.

ESTIMATING TOTAL COMMODITY COSTS

Estimating the total commodity costs involves calculating the cost of procuring the total program requirements arrived at at this step of the quantification. In addition to the product cost, other costs related to procurement, shipping/freight, handling, customs clearance, storage, and distribution may also be included in the total commodity cost estimate.

COMPARING TOTAL COMMODITY COSTS TO FUNDING AVAILABLE

Comparing the total commodity costs to the funding available consists of comparing the total commodity costs to the amounts of the funding commitments for procurement of products at the time of the quantification. 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. 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 essential medicines and other products for which funding is insufficient to procure the total program requirements, 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, different methods can be used to arrive at the final quantities of products to be procured, including the use of epidemiological profiles, and the ABC and vital, essential, nonessential (VEN) analyses. For example, this step could result in a reduction of the number of people that can be tested for HIV infection or the number of patients that will be able to initiate antiretroviral therapy (ART) within the period of the forecast.

DEVELOPING A SUPPLY PLAN

Once the total requirements and costs for the program have been estimated and (if needed) reconciled with the amount of funding available for procurement, a supply plan for the full period of the quantification must be developed. Typically, national quantifications are conducted to include the commodity needs for a two-year period to be able to identify the funding sources, mobilize additional resources to meet funding gaps if needed, and to ensure timely procurement and delivery of the commodities to the country. Developing the supply plan entails coordinating the timing of funding disbursements from multiple funding sources with procurement lead times and supplier delivery schedules to be able to ensure a continuous supply of HIV test kits to the country and to maintain stock levels between the established maximum and minimum levels.

IMPORTANCE OF STANDARDIZED TREATMENT GUIDELINES, TESTING PROTOCOLS, AND LABORATORY TESTING MENUS

A critical prerequisite for conducting quantification for any health commodity is the existence of clear, well-defined standard treatment guidelines (STGs), laboratory testing menus, and/or testing protocols for defining how specific products should be administered for treatment or used for testing. Standardization should precede quantification, as these guidelines form the basis of the assumptions in the forecasting exercise. In the case of new, rapidly expanding programs, the importance of standardized testing protocols is magnified, as sufficient quantities of commodities must be procured to allow for expansion.

In the absence of quality consumption data, quantification will likely be conducted using the demographic or morbidity-based method which depends on the existence of STGs, laboratory testing menus, and testing protocols. To enhance the accuracy of the quantification using this method, STGs, laboratory testing menus, and testing protocols must exist and must be clearly documented and disseminated. One key assumption in quantifications is that service providers are adhering to established standard guidelines. Without STGs, testing menus, and testing protocols, program planners have no way of estimating the types and quantities of products assumed to be used in a given time period. Many programs and services require multiple products to be available at the same service delivery point at the same time, and adherence to STGs can help ensure that the products are used as intended. Without standard protocols, significant quantities of some products could be wasted, while others could be stocked out.

BACKGROUND

Laboratory services are strategically critical to the success of service delivery in comprehensive public health programs. Specifically, laboratory services have been identified as one of the cornerstones on which those programs are built. As a result, the success of such programs is dictated, at least in part, by quality laboratory services that are able to keep pace with the increasing needs and demands of the programs, including ensuring continuous availability of essential laboratory commodities.

Ensuring continuous availability begins with the strengthening of the laboratory commodity management systems. To this end, quantification of laboratory supplies is a critical first step in

ensuring continuous supply. In many settings, however, laboratory services have been incapacitated by years of underfunding and neglect. Therefore, given recent and future plans of service expansion, it is even more critical for resource-limited countries to make significant investments in strengthening laboratory services, particularly in logistics management systems including quantification.

ISSUES SPECIFIC TO QUANTIFICATION OF LABORATORY SUPPLIES

Lack of Logistics Data

There are unique challenges to quantification of laboratory commodities. Ideally, forecasting should be based on logistics data because past usage data have been found to be the most representative indicator of future usage for forecasting purposes. However, as a direct result of the lack of attention paid to laboratory systems to date, very little data are recorded on usage and on stock levels of laboratory commodities. When data are available, often they are incomplete or unreliable and, therefore, cannot be used for quantification purposes.

In the absence of logistics data, demographic and morbidity data can be used for forecasting purposes. Although this approach is often used when forecasting commodities specific to a particular disease or condition or to a particular program (e.g., Reproductive Health and Family Planning), it is an approach that is extremely challenging to institute for laboratory commodities. Laboratory services are cross-cutting and are, therefore, difficult to tie to a particular condition or program. Even when it is possible to link a set of laboratory tests to a particular condition or program, it has proven to be impossible to anticipate additional laboratory tests that may be needed for any individual client. For example, although a client who is admitted to the hospital for malaria may routinely receive a malaria smear and hemoglobin estimation, it is not possible to predict what other tests may need to be administered as a result of complications that are associated with that specific patient.

Finally, service statistics can also be used for forecasting purposes. In using this methodology, one can use the number of tests conducted during a particular time period to forecast future needs. In the experience of the USAID | DELIVER PROJECT, most laboratories collect only service statistics, specifically on the number of tests conducted at each facility. Accordingly, the quantification process outlined as follows is based on the use of service statistics for forecasting.

Note: When more accurate logistics data on laboratory supplies become available, a usage-based (consumption-based) forecasting methodology should be used.

Large Number of Commodities to Be Managed

The second major challenge in the quantification of laboratory supplies is related to the sheer number of commodities that are required. In an effort to simplify the laboratory system and for the purpose of supply chain management, laboratory commodities can roughly be separated into three categories: reagents, consumables, and durables. For quantification, those categories will be refined even further.

Reagents

Reagents are chemicals and biological agents that are used in laboratory testing to detect or measure an analyte, the substance for which you are testing. Reagents vary widely in cost, stability, cold chain requirements, availability, and associated hazards.

Consumables

Consumables are items that are used once while performing a test and that are not reused. For quantification, there are multiple categories of consumables. Consumables can include test-specific items such as microscope slides and cover slips. Other consumables cut across all testing services and are classified as general laboratory consumables, such as bleach, alcohol, and gloves.

Durables

Durables are items that can be reused for multiple tests and include glassware that can be washed, sterilized, and reused. For quantification, this category also includes the equipment and instruments used for testing.

STEPS IN QUANTIFICATION

Regardless of the commodity being quantified, there are four main steps to the quantification process: forecasting demand, estimating requirements, estimating cost, and determining the quantity to procure. Product-specific differences will dictate the way each of the four main steps is completed.

PREREQUISITES TO QUANTIFICATION

A number of activities need to be completed before the quantification can be conducted. The information gained when completing those prerequisites will inform and guide the quantification.

DEFINE THE SCOPE AND PURPOSE OF THE QUANTIFICATION

The scope of the quantification will depend on various political, programmatic, financial, and environmental factors. For laboratory supplies, two initial factors that will help define the scope include (a) the laboratory services to be included and (b) whether or not the quantification is for the whole country or for one sector. National-level quantification is 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 laboratory services to meet the needs of the whole country
- Quantification by health sector (public sector, nongovernmental, or private sector) for the same laboratory services or for different laboratory services
- Quantification by program (e.g., quantification of laboratory commodities for public-sector ART program, sexually transmitted infection (STI) diagnostic and treatment, TB program diagnostic and treatment)
- Quantification by target population (e.g., to support pediatric ART patients)
- Quantification by geographic region (e.g., laboratory services for TB may exist in certain regions of the country but not in other regions)
- Quantification by funding source (government or donor organizations that fund procurement of commodities may require separate quantifications)

The purpose of the quantification and how it will address the program's needs must be identified. The following are examples:

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

The quantification exercise should also answer the following key questions:

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

DESCRIBE THE LABORATORY SYSTEM

Before beginning the actual laboratory supplies requirements quantification, it is important to clearly define the programs for which commodities are being quantified. For laboratory systems, given the fact that they support multiple programs, the definition should include not only the program but also the services for which the laboratory supplies are required.

From a supply chain management perspective, a program comprises all the laboratory services that have a common distribution pipeline. The laboratory supplies can be provided from the same funding source or from different funding sources, but if they all go into the same distribution pipeline, they are considered supplies for one program and require one quantification.

Conversely, the laboratory supplies can be provided from one funding source or from separate funding sources, but if they are distributed through separate distribution pipelines (e.g., 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 may vary by program.

Example 1: One Supply Chain, Quantification

In country X's public sector, laboratory commodities for general health services are funded by the government for all laboratories. The funds for laboratory supplies for blood safety are provided both by the government Global Fund grant and by the President's Emergency Plan for HIV and AIDS Relief (PEPFAR). The funds for laboratory commodities to support ART are provided by PEPFAR through the Centers for Disease Control and Prevention (CDC). However, all laboratory supplies are stored and distributed through the public-sector MOH supply chain as part of the national HIV & AIDS program. In this case, you would forecast demand separately for each of the funding sources and then aggregate the overall quantities required to determine the total quantities of laboratory supplies required by the MOH.

Example 2: Two Supply Chains, Quantifications

In country *Y*, you are asked to conduct quantification for the blood safety, voluntary counseling and testing (VCT), and sentinel surveillance (SS) activities. As you begin your questioning, you discover that laboratory supplies for VCT and SS programs are procured through the MOH Public Health Unit and MOH Logistics Unit and are distributed through the MOH regular essential drugs distribution system. The supplies for blood safety are donated by an NGO, briefly stored, and then distributed separately to the government blood collection sites by a private distributor under contract to the NGO. VCT and SS programs are separate programs, and they would require separate quantification exercises. However, within the MOH system, the first step in preparing the overall quantification is to forecast demand for VCT and SS separately, before final quantities required can be aggregated.

STANDARDIZE LABORATORY POLICIES AND PROCEDURES

Before conducting the standardization process, it is essential to obtain the following relevant laboratory policies and procedures:

- National laboratory policies
- National laboratory guidelines (including test menu and technique by level)
- Laboratory standard operating procedures (SOPs) by level, including quality control procedures

Quantification for laboratory supplies depends on test menus and test techniques used in the laboratory system. If national policies and procedures have been developed, they need to be reviewed and their use verified with key stakeholders to confirm that test menus and techniques identified in the policies and procedures are current and are practiced. If national policies and procedures have not been developed, a recommendation should be made that they be developed. As laboratory technologies rapidly evolve, guidelines need to be kept current with the most appropriate and accurate tests and techniques, which will help maintain a quality laboratory program. The development of national policies and procedures will facilitate the coordination of laboratory efforts at a national level, which reduces inefficiencies and wastage of resources in the laboratory system.

In the absence of detailed SOPs, key stakeholders should embark on the process of standardizing laboratory procedures. Standardization as a process includes defining the following elements of the laboratory system:

- Test menus by level
- Test techniques by level
- SOPs by test and by level
- Instrumentation by level

Each of the above elements should be defined and implemented across all laboratories at all levels of the system.

Because of the lack of logistics data for use in quantification, the standardization process becomes even more critical. When using service statistics data for the quantification of laboratory commodities, the volume of each test type and technique at each level of the system drives the

forecast. In a nonstandard system, the test types and techniques can reach into the hundreds, with subsequent commodity needs reaching into the thousands. This number presents an insurmountable obstacle to the quantification of these commodities. The standardization process provides a critical focus for the system and reduces the number of laboratory commodities needed to a manageable number.

For example, for a single hemoglobin test, approximately eight different manual techniques could be used to conduct the test. The different commodities required for each technique are listed in Table 1. If the quantification were to include all eight manual testing techniques, nine reagents, 14 consumables, and 22 durables or pieces of equipment would be needed.[1] Therefore, a total of 45 commodities would be required for use in one test, at one level of the system. If each laboratory at that level conducts 50 different tests using a variety of testing techniques, the commodity needs can easily expand to thousands of different commodities. Those needs can then be multiplied by the number of levels in the laboratory system, which results in a significant managerial and financial burden on the laboratory program.

Table 1. Manual Hemoglobin Tests and Laboratory Supplies Needed

Test Technique	Reagents	Consumables	Durables/Equipment
Filter Paper Comparison		• Filter/blotting paper • Sterile lancet • 70% alcohol • Cotton wool	• Color comparison chart
Copper Sulfate Method	• Copper sulfate	• Graduated transfer pipette • Capillary tube • Sterile lancet • 70% alcohol • Cotton wool	• Flasks • Weighing scale • Amber-tinted bottles
Hematocrit by Centrifuge	• Capillary tube • Sterile lancet	• 70% alcohol • Cotton wool	• Microhematocrit centrifuge
Lovibond Comparator	• Ammonia OR • Potassium ferricyanide • Potassium cyanide • Potassium dihydrogen phosphate • Surfactant	• Blood pipette • Sterile lancet • 70% alcohol • Cotton wool • Parafilm or foil	• Glass tubes • Lovibond comparator • Colored glass standards
Grey Wedge (BMS) Photometer	• Saponin powder • EDTA powder	• Toothpicks • Sterile lancet • 70% alcohol • Cotton wool	• BMS grey wedge photometer • Glass chamber for blood sample • Calibrating glass standard • Batteries (1.5 volt)

[1] Note that those test techniques are exemplary and additional commodities may be required for slightly different operating procedures. In addition, automated hemoglobin estimation techniques presented in this guide were not analyzed.

Table 1. Manual Hemoglobin Tests and Laboratory Supplies Needed, continued

Test Technique	Reagents	Consumables	Durables/Equipment
Sahli Method	• Hydrochloric acid	• Sterile lancet • 70% alcohol • Cotton wool	• Sahli hemoglobinometer • Sahli blood pipette • Dropper
HemoCue	• Cuvettes • Standard cuvettes • Sterile lancet	• 70% alcohol • Cotton wool	• HemoCue instrument • Batteries
Colorimetry-Hemiglobincyanide Method	• Potassium cyanide • Potassium dihydrogen phosphate • Surfactant	• Standard solution of hemoglobin • Graph paper • Tube labels	• Photoelectric colorimeter • Cuvettes • Test tubes • Watch or timer • Calibrated pipettes
TOTAL NUMBER:	**9**	**14**	**22**

The standardization of the laboratory system should take place through a consensus-building workshop that includes representatives from all levels in the health system that are providing laboratory services, the national public health laboratory or an equivalent institution, and key stakeholders involved in laboratory services.

The standardization process provides many benefits. It not only simplifies the quantification process but also contributes to quality testing throughout the system. The benefits of standardization include the following:

- High-quality, reliable, and consistent test results at all facilities
- Reduction in number of laboratory commodities
- Manageable supply chain for laboratory commodities

However, the standardization process is not without challenges. The following are some of the primary challenges:

- The tests and techniques agreed on in the standardized system may not be consistent with the tests and techniques that laboratory staffs have been previously trained on or that they are currently using in their laboratories. For example, the standardized system may call for a hemoglobin test to be conducted using the copper sulfate method at one level of the system. However, laboratory staff at that level might not have received any previous on-the-job training or academic training on the copper sulfate method. As a result, a large-scale training effort may be required to both inform laboratory staff about the new standardized system and to train them on the specific tests and techniques that the new system requires.
- The standardization process will almost certainly result in the obsolescence of equipment that had been in use in the nonstandard system. At each level, facilities will face the challenge of determining what to do with that equipment and of developing strategies to ensure that it will not be used under the standardized system.

- In many laboratories, the techniques used for testing and, consequently, the procedures followed have been determined by the availability of supplies. In a standardized system, the testing technique should be determined by the agreed-on test menu, technique, and instrumentation. Over time, this challenge should become less of an issue as the new tests and techniques and the associated commodities are phased into the laboratory system and as previously used commodities no longer required in the new system are phased out.

DETERMINE THE PERIOD OF THE FORECAST

Medium-term forecasts of laboratory commodity requirements for two to five years are recommended to assist in program planning and in mobilizing financial resources for procurement of laboratory supplies to support program expansion. The quantification and the costing of commodity requirements for procurement with available funds for a one-year period are recommended for short-term procurement planning and should include specific quantities of each product to be procured and a shipment delivery schedule for the year. Because of the rapidly changing environment inherent to laboratory systems, procurement plans for one year at a time are recommended, and such plans should be revised and updated every six months to reflect actual services provided and immediate plans for scale-up of services.

DETERMINE THE TARGET NUMBER OF TESTS TO BE CONDUCTED FOR EACH FORECAST YEAR

Although targets based on population and disease 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.

Note: An example of a standard test menu by level can be found in appendix A.

Nationally accepted program targets that are based on population and disease 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 laboratory services and manage the laboratory system supply chain. Realistic target test numbers should be based on the following:

- Current level of service provision (number of sites with trained and sufficient providers and infrastructure) and plans for expansion
- Current status of laboratory commodity supply and product availability at laboratories (stock status assessment at the facility and at the national level)
- Plans for financing and procuring laboratory supplies (sources and amounts of funding available for procurement, disbursement schedules, procurement mechanisms, and respective lead times)

COLLECT THE REQUIRED DATA

The final prerequisite to undertaking a quantification exercise is to collect the data that will be required before and throughout the quantification process. 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.

The minimum items that should be collected for use in the quantification process include the following:

- Average test numbers for each test technique by level
- Current inventory of equipment at each facility (necessary only if quantification includes procurement of equipment)
- Current stock status of all laboratory commodities throughout the system
- Expected shipments of laboratory commodities
- Rates of loss and wastage

In cases where key data are not available or are of very poor quality, it may be necessary to make estimates based on information gathered from key informants.

The following steps may be useful as a guide:

- Identify the type of program (e.g., MOH, NGO, faith-based, pilot or research).
- List all laboratory services provided (ART, TB, malaria, etc.) or those relevant for the quantification.
- Describe the model of services (the level and type of facilities where laboratory services are provided, such as a primary, secondary, tertiary, community-based, or outreach facility).
- Ascertain national guidelines for all laboratory testing services identified, including recommended or required testing protocols. (As part of the data collection process, verify the product registration and import requirements for those commodities.)
- Identify suppliers for each laboratory commodity.

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

- Identify all sources of financing for laboratory supplies (the government, international donor agencies, foundations, and private-sector donation programs).
- Determine the amount and duration of each financial commitment for laboratory commodity procurement. Identify specifically when funds will be available for use.
- Identify the procurement mechanisms and suppliers for each product (national bulk procurement, procurement through local distributors, or direct donation of product).
- Verify local and international pricing information for each type of laboratory commodity.
- Identify any cost-recovery or cost-sharing mechanisms in effect. Are there any costs associated with laboratory services (co-pay, free, sliding fee, partial subsidy)? What are the likely implications of the costs on client uptake of testing services?
- Identify any restrictions on financing regarding the types of laboratory supplies that can be procured (for example, funds from the Global Fund to Fight AIDS, Tuberculosis, and Malaria can be used only to procure laboratory supplies from World Health Organization's prequalified

suppliers, while PEPFAR funds might allow only for laboratory supplies to be procured from lists approved by the U.S. Food and Drug Administration or the CDC).

- Verify flexibility in amounts and availability of funding (for example, are there potential funds that can be reallocated to procure laboratory supplies, and how long would reallocation take?).

For logistics data and supply chain information (when using logistics data), here are the steps:

- Obtain national- and facility-level logistics data on usage of laboratory commodities, losses and adjustments, and stock on hand, if available.
- Calculate the wastage rate of laboratory supplies due to expiration, loss, or damage of the products that occur during storage, distribution and usage. Without data, this wastage rate is currently assumed to be 3% to 10% until data from stockcards become available.
- Determine whether an inventory control system is in place to manage laboratory supplies.
- Determine procurement lead times, supplier schedules, and lead times for delivery of supplies.
- Determine established buffer stock levels or maximum and minimum inventory levels, if available.
- Confirm facility order intervals.
- Determine the frequency and the timing of procurement procedures.

SOURCES OF DATA

The likely sources for much of the data needed for laboratory commodity requirements quantification are key informants and program documents in-country.

Key informants to interview include managers from national public health laboratory services, laboratory scientists representing all levels of the health system from both the public and the private not-for-profit sectors, and all stakeholders (NGOs, donors, etc.) supporting laboratory services.

Program documents that are likely to provide useful information include national laboratory policy and guidelines and reports of previous quantifications and procurements. Other sources of information can be the health management information system and the logistics management information system (LMIS), when available.

When forecasting demand for any of the commodity types, there are constraints in the type and quality of data available. Therefore, multiple assumptions will be required about specific tests and techniques by level, by capacity and quality of service delivery, by procurement and supplier lead times, and by status of the in-country supply pipeline. A consultative process with laboratory stakeholders will enhance accuracy and will ensure that the final quantities to order have been developed with input from a range of laboratory services providers. It is important to document the sources of information and input from key informants that are used to explain the assumptions for the quantification. The quantification should be reviewed and updated at least every six months and when any of the major assumptions change.

Examples of assumptions may include the following:

- The appropriate application of testing protocols

- The number of tests per level
- The forecasted demand for general consumables (commodities used across all procedures in the laboratory and sometimes outside the laboratory within the facility)
- The capacity of the supply chain to manage laboratory supplies
- The capacity of human resources
- The rate of wastage

USEFUL OUTPUTS

Laboratory commodity flow maps for each program or laboratory service are extremely useful visual outputs that can be developed during or after the data collection process to show the suppliers (funding sources) of the commodities, the commodities supplied by service, and the general distribution flow of the laboratory commodities from suppliers to points of use. Documenting the results of the data collection (and defining the program) will avoid double-counting some laboratory commodity requirements and failing to count others.

FORECAST DEMAND FOR LABORATORY PRODUCTS

The first step in the quantification process is to estimate the quantity required for each laboratory commodity to meet customer demand for the forecast period on the basis of service capacity and other programmatic factors that have already been taken into account through the definition of the scope of the quantification.

When quantifying for laboratory commodities, the forecasted demand is broken down into three distinct parts: (a) forecasted demand for reagents and consumables that are used per test, (b) forecasted demand for general consumables, and (c) forecasted demand for durables. Calculating forecasted demand for each of those categories of products requires a slightly different approach and different data. The following sections describe the steps that should be taken for each level of the system by category of product.

FORECASTING DEMAND FOR REAGENTS AND CONSUMABLES USED BY TYPE OF TEST

Assuming that the technique for each type of test has been defined in the standardization process, forecasting demand for reagents and consumables used by type of test requires the following steps:

DETERMINATION OF THE SPECIFIC COMMODITIES NEEDED

To forecast the demand for reagents and consumables used per test, one needs to determine the commodities used for each test, their basic units, the specifications, and the quantities needed to conduct that specific test. One or more products are often needed to conduct a single laboratory test, and each testing technique often uses different commodities. Therefore, there should be consensus on which commodities are needed to avoid further complicating an already complex system.

Once each commodity has been identified, its basic unit needs to be determined and specified[2] in consultation with laboratory services managers and scientists. Similarly, each test technique uses a specific quantity of a product to conduct the test. Therefore, the quantity of each commodity needed per test should also be determined. The amount of each commodity needed per test can be found in the SOPs, when available. If not available, international references, such as *District Laboratory Practice in Tropical Countries* (Cheesbrough 2000), should be sought to facilitate this process.

For example, to conduct a test for bacterial infections, one can use a gram stain blood smear technique. Table 2 identifies the commodities, including their basic unit, specifications, and quantity, which are needed for this particular test.

[2] Specifications provide the details that a procurement agent requires to procure the exact product needed for the test requirements.

Table 2. Commodities Needed per Test

Commodity	Basic Unit	Specifications	Quantity Needed per Test
Crystal Violet Stain	1 g	Stain powder, general purpose reagent (GPR)	0.025 g
Potassium Iodide	1 g	Powder, GPR	0.02 g
Iodine	1 g	Crystals, GPR	0.01 g
Acetone	1 L	Analytical reagent	0.0004 g
Neutral Red	1 g	Stain powder, GPR	0.0005 g
Microscope Slides	1 slide	Single frosted, precleaned, glass,76.2 mm x 25.4 mm x 1.2 mm	1 slide

Note: It is vital that formulas such as these be noted in the quantification assumptions to show how the quantity of reagents needed for each test was determined.

Determining the quantity of each commodity needed per test is further complicated by the nature of some of the laboratory supplies being used. The nature of such products, which will be used to conduct different tests, should be taken into account when determining the quantities needed per test. For instance, many laboratory reagents require reconstitution, which makes it difficult to determine the quantity needed per test.

In the preceding example, crystal violet stain is supplied in a powder form. If one is to use this particular stain, it must be reconstituted into a liquid form, which changes the basic unit from grams to milliliters (mL). SOPs will likely require a quantity of liquid (mL) for each test. If one is to determine the quantity in grams of crystal violet stain powder per test, the mL quantity will have to be converted to grams as follows:

- First, 1 g is used per 50 mL of distilled water.
- Then, 50 mL of solution is used for 40 tests.
- Therefore, 1 g of powder is used for 40 tests.
- Thus, 1 test uses 1 g/40 tests = 0.025 g/test.

Note that any commodity used for quality assurance and quality control purposes should be included in the forecasted demand.

MULTIPLICATION OF THE COMMODITIES NEEDED PER TEST BY THE AVERAGE TESTS DONE

For each test, the average number of tests performed per month at the particular level should be determined. This number will be multiplied by the quantity of each commodity needed to conduct one test. The results will finally be converted into yearly requirements and will give the commodities needed per facility on an annual basis for the specific test.

For example, if facilities at a particular level of the system conduct an average of 123 tests per month for bacterial infections by using a gram stain blood smear technique, the annual commodity requirements would be adjusted as follows in Table 3.

Table 3. Annual Commodity Requirements per Facility

Commodity	Basic Unit	Average Monthly Tests per Facility	Quantity Needed per Test	Quantity per Month	Quantity per Year
Crystal Violet Stain	1 g	123	0.025 g	3.075 g	36.9 g
Potassium Iodide	1 g	123	0.02 g	2.46 g	29.52 g
Iodine	1 g	123	0.01 g	1.23 g	14.76 g
Acetone	1 L	123	0.0004 g	0.0492 g	0.5904 g
Neutral Red	1 g	123	0.0005 g	0.0615 g	0.738 g
Microscope Slides	1 slide	123	1 slide	123 slides	1,476 slides

SUM OF THE COMMODITY REQUIREMENTS FOR ONE FACILITY

Up to this point, commodity needs have been expressed in terms of each particular test and technique. However, many laboratory commodities are used to conduct different types of tests. For this reason, it is important to sum requirements for each commodity across all the different types of tests conducted.

For example, crystal violet stain is used when testing for bacterial infections using the gram stain blood smear technique. It is also used when conducting a high vaginal swab (HVS) test using a microscopy technique. Assuming that those tests are the only tests and techniques that use crystal violet stain, the commodity requirements for each of the tests should be added together. Therefore, if 36.9 g of crystal violet stain are needed annually for gram stain blood smear tests and if 26.7 g of crystal violet stain are needed for HVS microscopy tests, a total of 63.6g of crystal violet stain are needed at the facility annually.

ROUNDUP OF COMMODITIES NEEDED FOR ONE FACILITY TO THE APPROPRIATE PACKAGING SIZE

Once total commodity needs for one facility have been determined, they should be rounded up to reflect the packaging size available for that specific commodity. For example, if facilities at a particular level of the system require 63.6 g of crystal violet stain annually, when considering the packaging size of each of the commodities required, the annual commodity requirements would be adjusted as follows in Table 4.

Table 4. Adjusted Annual Commodity Requirements per Facility

Commodity	Basic Unit	Quantity Needed per Year	Packaging Size	Adjusted Quantity per Facility	Packages per Facility
Crystal Violet Stain	1 g	63.6 g	25 g	75 g	3 packages

The same process should be undertaken for each commodity that is used at the facility.

Note: While it may seem logical to divide the total units required at a particular level by the packaging size to calculate the total number of packages required, it is important to remember that packages typically cannot be split or shared among different facilities.

To determine the yearly requirement for each product, for all laboratories, you must first round up to the packaging size or you will underestimate the total number of packages required. An inaccurate count would make the distribution of that product to the laboratories very challenging because the product is procured and distributed in packages, not in bulk. The only exception is when there is in-country capacity for repackaging products, which requires additional resources.

In the example that follows, this particular level has five laboratories. Each laboratory requires 63.6 g of crystal violet stain annually, which is procured in bottles of 25 g. In table 5, the facility rounds up to the packaging size.

Table 5. Roundup of Yearly Requirement to Packaging Size by Facility

Commodity	Annual Quantity Needed per Facility	Packaging	Adjusted Annual Quantity per Facility	Annual Packages per Facility	Number of at This Level	Annual Packages per Level
Crystal Violet Stain	63.6 g	25 g	75 g	3	5	15

In Table 6, rounding up to packaging size is done after the total quantity needed for the level is calculated.

Table 6. Roundup of Yearly Requirement to Packaging Size by Level

Commodity	Annual Quantity Needed per Facility	Number of Facilities at This Level	Total Quantity per Level	Packaging	Annual Packages per Level
Crystal Violet Stain	63.6 g	5	318 g	25 g	12.72

The preceding example demonstrates that about 13 bottles of 25 g of crystal violet stain would be required for all five laboratories, if rounding up to packaging size is done by level and not by facility. Equitably dividing 13 bottles among five labs would be very challenging and would mean opening and sharing three bottles among the five laboratories.

MULTIPLICATION OF FINAL COMMODITY REQUIREMENTS FOR ONE FACILITY BY THE TOTAL NUMBER OF FACILITIES

After annual commodity needs have been adjusted according to packaging size, the commodity requirements per level of the laboratory system need to be calculated. In the previous step, adjusted quantities needed per year were calculated for one facility. To determine the annual quantities needed for a particular level, the adjusted needs per facility are multiplied by the number of facilities in that level of the laboratory system.

To use data from the previous example, if there are 50 facilities in the particular level of the laboratory system, the quantity of crystal violet stain needed for that level would be the adjusted quantity needed per year for one facility—75 g or three packages—multiplied by 50 facilities. This process results in a total of 3,750 g or 150 packages of crystal violet stain needed annually for that level.

SUM COMMODITY REQUIREMENTS ACROSS THE LABORATORY SYSTEM

After commodity needs have been summed across all tests at each level, the final step in the process is to sum the commodity requirements across the laboratory system. This step will result in the total commodity requirements across all levels of the laboratory system. Those quantities will be referred to as the forecasted demand for reagents and consumables used per test.

FORECASTING DEMAND FOR GENERAL LABORATORY CONSUMABLES

Although quantifiable per test, general laboratory consumables are commodities used across many tests, and those items can even be found outside the laboratory (e.g., alcohol, gloves, disinfectant). Without question, the commodities are necessary to run a laboratory and must also be included in the forecast. Ideally, historical usage data would guide forecasting demand of general consumables. However, in the absence of logistics data, it may be necessary to make assumptions on the usage of those commodities, in consultation with laboratory personnel. It is critical to document the assumptions, as well as all assumptions made throughout the quantification process. (Refer to appendix B.)

Unlike the quantification of the supplies discussed so far, the steps of determining quantities required by type of test and technique are not applicable to general laboratory consumables. Hence, the first step in forecasting demand for general consumables is identifying each consumable, its basic unit, and the specifications. Next, the quantities required for one facility will be determined. Those quantities should then be rounded up to reflect the packaging size available for each commodity. As previously mentioned, this step should take place before multiplying the commodity requirement for one facility by the total number of facilities at that level. The final step is to sum the commodity requirements at all levels of the laboratory system. Those quantities will be referred to as the forecasted demand for general laboratory consumables.

FORECASTING DEMAND FOR DURABLES

For quantification, durables are divided into two categories: supplies and equipment, as shown in Table 7.

Table 7. Durable Supplies and Equipment

Durables	
Supplies	***Equipment***
Anaerobic Jar	Hematology auto-analyzer
Bijou Bottle	Binocular-powered microscope
Serological Pipette	Enzyme-linked immunosorbent assay (ELISA) reader and washer

Forecasting demand for durables will require the same steps as estimating the quantity required for general consumables. However, equipment is usually not included in the forecast unless specifically requested. On the one hand, if it is included, the step of rounding up quantities required for one

facility to the appropriate packaging size is not applicable. On the other hand, the forecast should always include spare parts that are likely to be needed during the forecast period, depending on a number of factors, including the following:

- Inclusion of spare parts in the equipment contract
- Availability of spare parts in the local market
- Availability of funds to procure spare parts

ESTIMATE REQUIREMENTS

The second major step in the quantification process is to adjust forecasted demand to account for product wastage, lead time stock, buffer stock, stock on hand, and quantity on order. At this step, an assessment of the in-country supply status is needed to calculate requirement estimates of each commodity expected to be stored, distributed, and used in the laboratory system. The requirement estimates should include the quantities of laboratory commodities required to meet forecasted demand and to fill the pipeline with adequate stock levels.

To estimate requirements for the next one-year procurement period, adjustments will need to be made to the forecasted demand to account for product wastage, lead time, buffer stock, stock on hand, and quantity on order. (Note: The adjusted quantity to order may be greater or less than the quantity forecasted, depending on current stock on hand and expected usage rates.) The quantity to order may also need to be further adjusted to reflect current storage and distribution capacity, especially for products that may require refrigeration.

ADJUSTMENT OF TOTAL FORECASTED DEMAND FOR PRODUCT WASTAGE, LEAD TIME STOCK, AND BUFFER STOCK

Using Excel spreadsheets or other software designed to calculate the quantity to order of each laboratory commodity, the total quantity of each laboratory commodity required at all levels of the system for the forecast period is entered as the base number from which all adjustments will be made.

PRODUCT WASTAGE

It is important to account for product wastage, including product loss through spillage, through incorrect measurement, or through damage during use. Initially, product wastage rates can be assumed to be 10% of the total quantity required. However, product wastage rates can drop with improved testing skills, appropriate equipment, and infrastructure to around 3% of the total quantity required.

LEAD TIME STOCK AND BUFFER STOCK

The estimated requirements needed to fulfill demand during the forecast period also need to be adjusted to include lead time and buffer stock levels throughout the system during the forecast period. Lead time stock is the laboratory commodity stock kept on hand and used between the times the new stock is ordered and the new stock is received and available for use. Buffer stock required is the laboratory commodity stock kept on hand to protect against stockouts caused by delayed deliveries, markedly increased demand, or other unexpected events.

Buffer stock is measured in months of stock and is required for the calculated annual commodity requirements. It is, therefore, calculated by dividing the annual requirement by 12 to determine

monthly requirements, which will then be multiplied by the number of months of buffer stock required to cover for uncertainties, such as a sudden increase in usage or delays in delivery of supplies.

Determining the lead time stock required is done in much the same way that determining the buffer stock requirement is done. For each laboratory commodity, multiply the previously calculated average monthly requirement by the number of months of lead time stock required to cover stock used between the time new stock is ordered and the time that new stock is received and available for use. This formula will result in the total lead time stock required. Initially, lead time levels may also include the time required for preparation of the quantification, for allocation and disbursement of funds, for contracting of suppliers, for procurement, for shipment delivery, for customs clearance, for inspection, and for receipt of products into the central warehouse.

Note: It is very important to involve the in-country counterparts when setting the buffer stock and lead time stock levels.

Lead time stock and buffer stock requirements are then added to the total forecasted demand that has been adjusted for product wastage.

Adjusted Requirements Estimate	=	Total Forecasted Demand	+	Estimated Requirements for Product Wastage	+	Estimated Requirements for Lead Time and Buffer Stock

FURTHER ADJUSTMENT OF THE REQUIREMENTS ESTIMATE TO ACCOUNT FOR EXPECTED STOCK ON HAND AT THE BEGINNING OF THE PERIOD

The adjusted requirements will need further adjustment to account for the estimated stock on hand (SOH) at the beginning of the forecast period. The estimated stock on hand is calculated using the following formula:

Estimated SOH at Beginning of Forecast Period	=	Current SOH	+	Quantity on Order	–	Estimated Usage	+/–	Estimated Future Losses and Adjustments

It is important to remember that the current SOH includes the stock balances in each of the laboratories included in the quantification, as well as any stock stored at central or intermediate level storage.

For more details on this calculation, see the *Contraceptive Forecasting Handbook for Family Planning and HIV & AIDS Prevention Programs* (DELIVER 2000).

To arrive at the actual quantity to order, subtract the estimated SOH at the beginning of the forecast period from the adjusted requirements estimate. The resulting annual quantity to order is the quantity of each laboratory commodity needed to ensure full supply at laboratories for the forecast period.

Quantity to Order	=	Adjusted Estimated Requirements	–	Estimated SOH at Beginning of Forecast

Note: If a logistics system has not been designed, logistics data on SOH and usage of laboratory supplies will not be available at the time the quantification is conducted. Assumptions may need to be made about national stock and facility stock levels, lead times for funding disbursement and procurement actions, recommended buffer stocks, and supplier delivery schedules and lead times.

Note: Additional adjustments in the quantity to order may be required at this point in the quantification to reflect the volume of product that can be adequately stored and distributed to ensure the quality and security of the laboratory commodities. Using sources of information on packaging and shipment sizes, the packaging dimensions of laboratory commodities may be used to calculate the volume of incoming shipments and may be compared to actual storage space available in-country. The estimates of shipment volume and storage capacity are particularly important for reagents that may require refrigeration.

ESTIMATING COST REQUIREMENTS

At this stage in the quantification process, the total cost estimate of the requirements is calculated. Those results can then be used for program planning and for resource mobilization.

Updated sources of information on reagents and laboratory consumable prices, supplier rates, preferential pricing, and eligibility for donation programs will be needed to estimate the cost of the quantities of each laboratory commodity to be ordered. In addition, information on the cost of insurance and freight, customs clearance and duties, and in-country storage and distribution costs may need to be added to the cost of the quantities of laboratory supplies to be procured (if not included in supplier rates, budgeted for through other mechanisms, or waived).

Using Excel spreadsheets or other software, enter the quantity to order as the total number of packing units to be ordered for the forecast period.

Using the cost per pack as the unit of measure for calculating the total cost estimate, multiply the quantity to order of each commodity by the cost per pack to arrive at the total cost per commodity for the forecast.

$$\text{Total Cost per Commodity} = \text{Quantity to Order} \times \text{Cost per Pack}$$

Depending on the purpose of the quantification and on the available sources of funding for procurement of laboratory supplies, additional cost comparisons between suppliers may be required. Using the same approach, one may need to apply different supplier rates and costs per pack to arrive at alternate total cost scenarios that should be considered when making decisions on funding sources and allocations for procurement.

RECONCILING COST OF REQUIREMENTS WITH AVAILABLE FUNDING AND ADJUSTING QUANTITY TO PROCURE, IF NEEDED

The final step in the quantification process is to compare available funding to the cost estimate and to adjust the quantity to procure, if needed. Those results can then be used for short-term procurement planning.

The final decision on the quantities to procure will be determined by the amount of funding available for procurement of laboratory supplies. Where sufficient funding is available, the final quantities to procure each laboratory commodity will be the same as the quantity to order resulting from the quantification.

In the current environment of increasing financial resources for laboratory supply procurement, funding may be adequate to ensure full supply for targeted tests for the period of the forecast where service delivery and supply chain capacity exist. In other situations, the purpose of the quantification may be to determine how many laboratory tests can be provided in a year given a specific amount of funding available. A map of funding commitments can be used to compare forecasted demand with available funding.

THE USAID | DELIVER PROJECT recommends flexible regular shipments in which shipment quantities can be adjusted to respond to uptake in testing services, changes in testing demand, and rates of consumption of laboratory supplies. Agreements with suppliers may also need to have the flexibility to delay shipments of annual quantities procured if uptake of services does not meet expected demand.

SUMMARY OF CHALLENGES AND LESSONS LEARNED IN QUANTIFICATION OF LABORATORY COMMODITIES

CHALLENGES

The USAID | DELIVER PROJECT identified a number of challenges in preparing quantifications of national-level laboratory supplies. The challenges have been summarized and were used to inform the approach to quantification presented in this guide. They include the following:

- Data on usage of laboratory supplies are limited and, when available, often are unreliable or insufficient for use in quantifying requirements for laboratory supplies.
- Standard operating procedures for testing services are often lacking. Laboratories tend to develop their own SOPs based on personnel experiences, which results in inconsistent techniques and procedures across laboratories at the same level.
- Testing procedures and techniques have been dictated by availability of supplies rather than by standard protocols.
- Implementation of a standard system can pose challenges in training all laboratory personnel in the recommended testing techniques. Furthermore, the question of functional machines not used in the application of the recommended SOPs is a pending issue in many cases.
- Program targets may not take into account the testing capacity to provide services and supply chain capacity to finance, procure, and manage greater volumes of laboratory supplies.
- Multiple sources of funding, procurement mechanisms, and distribution channels are used for laboratory supplies.
- Quantification capacity at the country level and at the program level is limited.

- Communication and coordination between policymakers, service providers, funding sources, and procurement agents on issues related to the selection, quantification, and procurement of laboratory supplies are lacking. As a result, incompatibility of reagents and equipment procured from different sources is a frequent issue.

Quantification and procurement occur when funding becomes available, when identifying commodity needs, and when mobilizing resources for procurement rather than as a program planning activity. This lack of planning has led to stockouts and to expensive emergency procurements.

LESSONS LEARNED

The following lessons were also identified and documented and have been incorporated into the approach to quantification presented in this guide. The lessons include the following:

- The quantification exercise itself is time and resource intensive. Therefore, adequate time and resources to conduct the quantification exercise should be planned for and budgeted for.
- Currently, quantifications are based on informed assumptions, but they will become more evidence based over time as the availability and quality of data improve. Therefore, simultaneous efforts to strengthen the LMIS are encouraged.
- In the absence of logistics data, the most appropriate methodology for quantifying laboratory supplies seems to be service statistics, using the number of each test performed over a given period, except for general laboratory consumables and durables. The latter commodities require assumptions based on usage data, in consultation with laboratory personnel.
- Quantification requires a consultative process with multiple stakeholders to inform the assumptions about the selection, quantification, and procurement of laboratory supplies.
- Before quantifying laboratory supplies, one should conduct a standardization exercise to either develop or update test menus, techniques, testing procedures, and equipment for each level of the health system.
- The standardization process should always be a consultative workshop, with representatives from all programs and levels providing testing services, donors, and all key players in laboratory services. This is a critical step toward transferring ownership of the results to in-country stakeholders. The meetings can also help mobilize resources, set expectations, and promote collaboration and coordination, especially if delays in commodity availability occur.
- The quantification should be based on realistic program plans and on available financing.
- The results of the quantification should be used to determine specific order quantities and shipment schedules for short-term procurement planning on the basis of available funding.
- The results of the quantification should also be used for medium- and long-term program planning and resource mobilization for laboratory testing services.
- The quantification should be reviewed and updated at least every six months, and procurement plans should be adjusted accordingly.

APPENDIX A

TYPES OF DATA USED FOR FORECASTING CONSUMPTION OF HEALTH COMMODITIES

The ultimate goal of the forecasting step in the quantification process is to arrive at the quantities of each product that will be consumed or used for a particular service or treatment during a specified period. Countries and programs will vary in terms of the type of data that are available for forecasting, and the quality of those data. In general, it is recommended to produce and compare different forecasts using more than one type of data. In practice, multiple challenges in the availability and quality of the data may result in forecasts that are based on only one source of data and informed estimates of demand from qualified experts in the field of practice for which the commodities are needed.

Four basic types of data can be used for forecasting consumption of health commodities: consumption data, service statistics data, demographic/morbidity data, and target data. The goal is to use these different data types to determine the quantities of each product that will be consumed during a given period. With consumption data, the starting point is the quantities of products dispensed. With service statistics data, demographic/morbidity data, and target data, the starting point is not quantities of products but number of people, number of cases of a disease or episodes of a health condition, or number of visits. The number of people expected to be served, number of episodes expected, or the number of visits expected must then be translated into the estimated quantities of products that will be consumed.

1. Consumption Data

Consumption data are historical data on the actual quantities of a product that have been dispensed to patients or used at a service delivery point within a given time period, and are typically reported per month or per quarter. Daily consumption data can be found in pharmacy dispensing registers, laboratory registers, or other point of service registers. Where a well-functioning LMIS captures and aggregates these data from service delivery points, aggregated consumption data can be found in monthly and annual facility-level and program-level reports. For antiretroviral drugs (ARVs), consumption data would be the actual quantity of each ARV dispensed to ART patients. For HIV tests, consumption data or "usage data" are the actual number of HIV tests used over a given period. For laboratory supplies, consumption data are the actual number of laboratory commodities used.

When using consumption data, the forecast is based on the quantities of HIV tests used in the past. Consumption data are most useful in mature, stable testing programs that have a full supply of test kits and where reliable data are available. One caution on using consumption data is that data on past consumption of HIV tests will not be predictive of future use in a scaling-up environment. Also, if the program has experienced stockouts of test kits, past consumption data will underestimate what the consumption would have been if HIV test kits had been continuously available at all HIV testing facilities.

2. Service Statistics Data

Service statistics data are also historical, program-level or facility-level data on the number of patient visits to facilities, the number of services provided, or the number of people who received a specific service or treatment within a given time period. Service statistics data can be found in program monitoring reports, HMIS data, facility-level data on service utilization and attendance rates, or in patient records. In some programs, the LMIS captures a limited number of service statistics. For ARVs, service statistics data would be the total number of ART patients on treatment at a facility, or perhaps the total number of patient visits to a facility at a point in time. For HIV tests, service statistics would be the total number of clients tested during a certain period. For laboratory supplies, service statistics are the total number of tests performed in a certain period (e.g., CD4 count tests performed in a given quarter).

3. Demographic/Morbidity Data

Demographic/morbidity data are data on the proportion of a specific population estimated to be affected by a given health condition that requires a specific treatment, or estimates of the number of episodes of a given health condition that will occur in a common denominator of the population (e.g., number of episodes per 1,000 or per 100,000 population). The quantities of drugs needed to treat the estimated population or an estimated number of episodes of the disease or health condition per year are then calculated based on standard treatment guidelines. In some cases, these population-based figures are further refined to estimate a more segmented population that may actually have access to a health facility where the services are provided. Demographic/morbidity-based estimates are often used to estimate the total unmet need for a service or treatment in a program or country, and therefore would represent the uppermost bounds of the potential drug requirements might be for a program.

For ARVs, demographic/morbidity data would represent estimates of the total population that would be HIV positive, eligible to receive ART, and have access to care and treatment services. For HIV tests, demographic/morbidity data would estimate the total population and how many people are expected to receive an HIV test, and then apply the HIV prevalence rate. For laboratory supplies, demographic/morbidity data would estimate the total population that is affected by a particular disease or illness, and how many of those would access services.

Because demographic/morbidity estimates are not based on actual service delivery or use of commodities at health facilities but on broader population estimates of potential need, forecasts based on such data tend to overestimate forecast consumption and are not generally appropriate for estimating the quantities of drugs to be procured. Sources of demographic and morbidity data include census surveys, specialized health surveys, epidemiological surveillance data, or research

studies. Typically, when data are limited, nonexistent, or of poor quality, demographic/morbidity data may be used to estimate drug requirements.

4. Program Target Data

Political or programmatic targets typically are not related to the actual numbers of patients being served or who can be served by a program, the volume of commodities being used at health facilities, or the capacity of the supply chain to manage the volume of commodities required. Broad program targets of this type are best used for advocacy and resource mobilization, and thus generally are not appropriate as estimates for procurement of commodities. Sources of program target data include program planning documents, national policy and strategy documents, and materials published for dissemination and advocacy.

On the other hand, program targets may also be based on current levels of service delivery adjusted to reflect program expansion plans over a specified period. They are usually a combination of service statistics data and estimates or projections of increased program coverage and should ideally take into consideration funding available, service delivery capacity, and supply chain capacity to manage increased volumes of commodities. For procurement purposes, these are the types of program target data that are recommended for quantifying program commodity requirements.

APPENDIX B

TEST MENU AND TECHNIQUE BY LEVEL

Tests Performed at Health Center Laboratory

Laboratory Test	Standard Technique
❒ Hemoglobin estimation	❒ Oxyhemoglobin, Lovibond comparator
	❒ Cyanmethemoglobin, Sahli
❒ Blood slide for hemoparasites	❒ Field stain
❒ Stool microscopy for parasites	❒ Direct saline, iodine
❒ Sputum for AFB	❒ ZN stain
❒ Skin slit for AFB	❒ ZN stain
❒ Urine sediment microscopy	❒ Direct microscopy
❒ Urine protein, sugar	❒ Uristix
❒ Syphilis screening	❒ Rapid plasma reagin (RPR)/ VDRL carbon antigen
❒ Sickle cell screen	❒ Sodium metabisulphite
❒ Genitourinary tract specimens	❒ Wet prep/Gram stain/KOH
❒ Pus swabs	❒ Gram stain
❒ Bubo aspirate (plague)	❒ Wayson staining
❒ HIV screening	❒ Rapid screening kits
❒ Blood grouping	❒ Tube method
❒ Rhesus typing	❒ Tube
❒ Total white cell count	❒ Manual, Hemocytometer using Turks fluid
❒ Differential white cell count	❒ Manual, using stained thin film
❒ Cerebrospinal fluid microscopy	❒ Gram/Leishman/Turks fluid
❒ Cerebrospinal fluid chemistry	❒ Turbidimetric

Additional Tests Performed at District Hospital Laboratory

❒ Concentration technique	❒ Buffy coat (Knotts)
❒ Blood	❒ Formal ether
❒ Stool	
❒ Urine qualitative chemistry (protein, sugar, ketones, blood bilirubin, urobilinogen)	❒ Uristix
❒ Skin snip for microfilaria	❒ Saline direct
❒ Collection and fixation of cytological smears	❒ Formalin
❒ Collection and fixation of histological specimens	❒ Formalin

Tests Performed at Regional Hospital Laboratory

Laboratory Test	Standard Technique
❒ Hemoglobin estimation	❒ Hematology analyzer
❒ Total white cell count	
❒ Differential blood counts	
❒ Platelet count	❒ Hematology analyzer
❒ Reticulocyte count	
❒ Blood indices	
❒ CD4/CD8 count	❒ Flow cytometer
	❒ Non-cytofluorometric
	❒ Manual
❒ Viral load	❒ HIV RNA
	❒ Real Time PCR
	❒ Heat Dissociated p24 antigen
	❒ Cavidi RT
❒ Sickle cell screening test	❒ Sodium metabisulphite
❒ Blood slide examination for parasites	❒ Manual microscopy (field)
	❒ Concentration
❒ Film comment	❒ Manual microscopy- Romanosky
❒ Stool microscopy	❒ Direct saline/iodine concentration
❒ HIV screening	❒ Rapid screening kits
❒ Hb types	❒ Electrophoresis
❒ Serum proteins	❒ Electrophoresis
❒ Hepatitis B screening	❒ Rapid ELISA
❒ Syphilis screening	❒ RPR/VDRL carbon antigen
❒ Serum bilirubin	❒ Chemistry auto-analyzer (or Manual Photometer)
❒ SGOT (serum)	
❒ SGPT (serum)	
❒ Alkaline phosphatase (serum)	
❒ Renal function tests	

Tests Performed at Regional Hospital Laboratory, continued

Laboratory Test	Standard Technique
❒ Blood glucose	
❒ Serum electrolytes	
❒ Total protein	
❒ Examination of cerebrospinal fluid (CSF) for yeast	❒ Negative staining-India ink
❒ Examination of CSF, pus, deposit, etc., micro-organisms	❒ Gram stain
❒ Culture	❒ Aerobic
	❒ Anaerobic
	❒ CO2
❒ Drug sensitivity	❒ Disc diffusion
❒ Microscopy for plague	❒ Wayson staining
❒ Processing biopsy	❒ Hematoxylin and eosin
❒ Semen analysis	❒ Microscopy
❒ Cytology	❒ Microscopy
	❒ Pulp smear
❒ Sputum for TB	❒ ZN stain
❒ Urine sediment microscopy	❒ Direct microscopy
❒ Urine chemistry	❒ Uristix
❒ Genitourinary track specimens	❒ Wet prep
	❒ Gram
	❒ KOH
❒ Blood group, type and cross matching	❒ Tube method
❒ Skin snip for microfilaria	❒ Saline direct
❒ Examination for fungi	❒ KOH
❒ Confirmatory test for syphilis	❒ TPHA

APPENDIX C

LIST OF CONSUMABLES

Consumables Used for a Specific Test

Anaerobic sachets
Bijou bottles
Blood culture bottles
Blood lancets
Blotting paper
Capillary tubes
Centrifuge tubes
Cotton swabs
Cover slips
Gauze mesh
Heparinized capillary tubes
Immersion oil
Khan tubes
Lancet
Microaerophilic sachets
Microscope slide
Microtainer
Microtitre plates
Pipette tips
Pipette tips (filtered)
Prepacked iodine swabs
Printer paper for CBD machine
Printer paper for CD4/CD8 machine
Sputum container
Stool container
Test tubes
Universal containers
Vacutainer, red top
Vacutainer, grey top
Vacutainer, EDTA
Vacutainer needles
Vacutainer needle holder

General Consumables

Alcohol
Applicator stick
Autoclave tape
Cotton wool
Face masks
Filter paper
Gloves
Immersion oil
Lens tissue
Lysol
Methylated spirit
Petri dish (if these are disposable)
pH paper
Printed labels
Soap
Sodium hypochlorite
Xylene

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