



A Commodity Management Planning Guide for the Scale-Up of HIV Counseling and Testing Services

Helena Walkowiak
and Michael Gabra
with Gloria Sangiwa and
Ya Diul Mukadi



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Revised edition of *Commodity Management in VCT Programs: A Planning Guide*

Helena Walkowiak and Michael Gabra
Management Sciences for Health
Rational Pharmaceutical Management Plus Program

In collaboration with
Gloria Sangiwa and Ya Diul Mukadi
Family Health International

December 2008



This report was made possible through support provided to the Rational Pharmaceutical Management Plus Program (RPM Plus) by the U.S. Agency for International Development (USAID), under the terms of cooperative agreement number HRN-A-00-00-00016-00. The opinions expressed herein are those of the authors and do not necessarily reflect the views of USAID.

About RPM Plus

RPM Plus works in more than 20 developing and transitional countries to provide technical assistance to strengthen pharmaceutical and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

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Formed in 1971, FHI is among the leading and most established nonprofit organizations active in international public health with a mission to improve lives worldwide through research and programs in public health. With nearly 2,300 staff globally and programs in over 65 countries, FHI delivers comprehensive services in HIV/AIDS prevention, treatment, care and support through partnerships with national governments, research institutions, the private sector, and non-government and community organizations. FHI also serves a wide variety of funders, including USAID and the President's Emergency Plan for AIDS Relief; the Bill & Melinda Gates Foundation; and the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria in addition to several other multilateral, bilateral, UN, and private sector organizations. For more details about FHI please visit the website www.fhi.org.

Recommended Citation

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Walkowiak, H., and M. Gabra, with G. Sangiwa and Y. D. Mukadi. 2008. *A Commodity Management Planning Guide for the Scale-Up of HIV Counseling and Testing Services*. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.

First edition published as Walkowiak, H., and M. Gabra, with Eric van Praag, Deborah Boswell, Gina Dallabetta, Gloria Sangiwa, Deborah Murray, Jane Harriet Namwebya, and John Cutler. 2002. *Commodity Management in VCT Programs: A Planning Guide*. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.

Rational Pharmaceutical Management Plus Program
Center for Pharmaceutical Management
Management Sciences for Health
4301 N. Fairfax Drive, Suite 400
Arlington, VA 22203
Phone: 703.524.6575
Fax: 703.524.7898
E-mail: rpmpplus@msh.org
URL: www.msh.org/rpmpplus

ACKNOWLEDGMENTS

The Management Sciences for Health (MSH) and Family Health International (FHI) authors of this revised and expanded second edition gratefully acknowledge the collaboration of Eric van Praag, Deborah Boswell, Gina Dallabetta, Deborah Murray, Jane Harriet Namwebya, and John Cutler, all of FHI, in the first edition.

MSH and FHI also would like to acknowledge the contributions of the participants of the satellite session “Managing Commodities for Voluntary Counseling and Testing (VCT) in the Era of Scaling Up” held at the 2003 13th International Conference on AIDS and STIs in Africa in Nairobi. Suggestions for changes to the 2002 edition of this document and the sharing of experiences by the participants are gratefully acknowledged. The authors also thank the presenters, facilitators, and organizers of the satellite session.

MSH and FHI staff who contributed case studies, experiences, and lessons learned to this update are gratefully acknowledged—

- Laila Akhlaghi, MSH/RPM Plus
- Hare Ram Bhattraai, MSH/RPM Plus
- Gege Buki, MSH/RPM Plus
- Tresphor Chisanga, FHI/Zambia HIV/AIDS Prevention, Care and Treatment (ZPCT) Partnership
- Cecilia Chitambala, MSH/ZPCT Partnership
- Gabriel Daniel, MSH/RPM Plus
- Oliver Hazemba, MSH/RPM Plus
- Charles Kagoma, MSH
- Enock Kajawo, MSH/Reducing Childhood Morbidity and Strengthening Health Care Systems in Malawi (RCM) Project
- Cynthia Kamtengeni, MSH/RPM Plus
- Negussu Mekonnen, MSH/RPM Plus
- Catherine Mundy, MSH
- George Muyunda, MSH consultant
- Maurice Mwale FHI/ZPCT Partnership
- Lameck Nyirenda FHI/ZPCT Partnership
- Erik Schouten, MSH/RCM Project–Malawi
- Belen Tarrafeta, MSH/RPM Plus
- Rudi Thetard, MSH/RCM Project–Malawi
- Haile Wubneh, MSH/RPM Plus

The invaluable assistance of Abiola Johnson in collating the information for the case studies that enrich this document is highly appreciated.

The authors also thank the following other reviewers and contributors—

- Bristol Chemba, National Coordinator, Zambia Voluntary Counselling and Testing Services

- Clement Mulenga, Data Manager, Zambia Voluntary Counselling and Testing Services
- Mrs. Ngulube, Nurse-in-Charge of VCT Services, Mahatma Gandhi Clinic, Kabwe, Zambia
- Eva Wonani, District Clinical Specialist–Kabwe, Zambia

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ACRONYMS

AIDS	acquired immunodeficiency syndrome
CAMERWA	Centrale d’Achat de Médicaments Essentiels du Rwanda [Rwanda]
CBO	community-based organization
CDC	U.S. Centers for Disease Control and Prevention
CHAI	Clinton Foundation HIV/AIDS Initiative
DBS	dried blood spot
ELISA	enzyme-linked immunosorbent assay
FHI	Family Health International
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
GMP	Good Manufacturing Practices
HAPCO	HIV/AIDS Prevention and Control Office [Ethiopia]
HIV	human immunodeficiency virus
HIV-1	human immunodeficiency virus type 1
HIV-2	human immunodeficiency virus type 2
JICA	Japan International Cooperation Agency
MoH	ministry of health
MSL	Medical Supplies Limited [Zambia]
MSH	Management Sciences for Health
NORAD	Norwegian Agency for Development Cooperation
NGO	nongovernmental organization
PCR	polymerase chain reaction
PEPFAR	U.S. President’s Emergency Plan for AIDS Relief
PITC	provider-initiated HIV testing and counseling
PMTCT	prevention of mother-to-child transmission [HIV]
PSM	Procurement and Supply Management [Global Fund]
RCM	Reducing Childhood Morbidity and Strengthening Health Care Systems in Malawi Project [MSH]
RPM Plus	Rational Pharmaceutical Management Plus Program
SCMS	Supply Chain Management System project
SOP	standard operating procedure
STI	sexually transmitted infection
TB	tuberculosis
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNFPA	United Nations Population Fund
UNICEF	United Nations Children’s Fund
USAID	U.S. Agency for International Development
VCT	voluntary counseling and testing
VEN	vital, essential, nonessential (analysis)
WHO	World Health Organization
ZPCT	Zambia HIV/AIDS Prevention, Care and Treatment Partnership
ZVCTS	Zambia Voluntary Counseling and Testing Services

INTRODUCTION

This publication is an update of *Commodity Management in VCT Programs: A Planning Guide*, published in 2002. The update aims to achieve the same goal, namely, to provide practical guidance on commodity management issues related to establishing, managing, and scaling up a variety of HIV counseling and testing¹ options, including voluntary counseling and testing (VCT) programs, to meet different needs in diverse settings at both national and point-of-service levels. This guide is intended to assist a range of audiences—including national program planners and policy makers, donors currently supporting or planning to support HIV counseling and testing service delivery, and HIV counseling and testing service implementers—in systematizing their approaches to strengthening and scaling up HIV counseling and testing services.

In addition to updating the information included in the first edition, this edition incorporates real-life experiences in strengthening commodity management systems and recognizes the important contributions of national governments and their partners, such as the Supply Chain Management System (SCMS) project funded by the U.S. government as part of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), the Clinton Foundation HIV/AIDS Initiative (CHAI), the World Health Organization (WHO), and the United Nations Children's Fund (UNICEF), in improving access to HIV test kits and other important commodities. New additions in this update include—

- A focus on strengthening commodity management systems to support the scaling up of HIV counseling and testing services. Country experiences, lessons learned, and successful, replicable interventions for going to scale—and particularly for strengthening coordination and communication—are shared.
- Discussion of the commodity management issues for supporting different service delivery models for HIV counseling and testing, including new approaches such as mobile HIV counseling and testing.
- Information on new tools and resources for managing commodities, including an expanded section on experiences in strengthening the commodity management information system to support the scale-up of HIV counseling and testing.
- A new chapter on key commodity management considerations for implementing changes in national HIV testing algorithms.

This document is more relevant to higher-prevalence and generalized epidemic settings and may not reflect the realities in some settings, such as Asia, Latin America and the Caribbean, the

¹ For the purposes of this document, HIV counseling and testing is used as an umbrella term that encompasses models for offering HIV counseling and testing for different needs in different settings, such as provider-initiated HIV testing and counseling (PITC) and traditional VCT in which clients self-refer, and includes community-based approaches and outreach services.

Middle East, or Eastern Europe. Furthermore, although the recommendations for strengthening HIV testing supply and information systems will apply to many settings in countries with high prevalence and generalized epidemics, they may not reflect the situation on the ground in all countries.

Defining Commodities

In the context of health services, commodities include reagents and test kits, laboratory equipment and supplies, condoms, and other medical supplies and equipment such as specimen collection tools. For the purposes of HIV counseling and testing, commodities may also include such items as videos and information leaflets and components of “basic preventive care packages.” (See the subsequent section called Commodities for HIV Counseling and Testing—More Than HIV Test Kits.) The term “pharmaceutical” encompasses medicines, vaccines, and health commodities as described above.

One of the first steps for planners and implementers of HIV counseling and testing services is to decide what items will be included on their HIV counseling and testing commodity list. Although the focus of this document is the management of commodities for HIV counseling and testing, the availability of medicines and commodities for related services is recognized as being critical to the success of comprehensive HIV/AIDS programs. Requirements of medicines and commodities for related services will depend on the HIV counseling and testing service delivery model selected and program access to referral mechanisms. Therefore, issues pertaining to the wider range of HIV-related commodities are discussed where appropriate.

Why Commodities Are Critical to the Success of HIV Counseling and Testing

The Key Elements of Any HIV/AIDS Program Are—

- Prevention of new infections
- Treatment and care of those already infected
- Mitigation of the effects of the epidemic on individuals and communities

HIV counseling and testing provides entry to an extended range of HIV/AIDS support, care, and prevention activities. Since the first edition of this guide was published, commitment to improve access to HIV counseling and testing has increased significantly in developing economies. In May 2006 at a Special Summit on AIDS, Tuberculosis and Malaria organized by the African Union in Abuja, Nigeria, African heads of state committed to ensure that at least 80 percent of target populations have access to voluntary

HIV counseling and testing services by 2010. Similarly, in June 2006, the United Nations (UN) General Assembly endorsed the scaling up of HIV prevention, treatment, care, and support to achieve a goal of universal access by 2010. However, WHO, the United Nations Programme on HIV/AIDS (UNAIDS), and UNICEF report that demographic and health surveys conducted in 12 high-burden sub-Saharan African countries from 2003 to 2005 showed that the median percentages of men and women in the general population who had ever been tested for HIV and

had received the result was 12 percent and 10 percent, respectively.² A subset of the surveys that incorporated HIV testing showed that the percentage of people living with HIV who knew their status ranged from 12 to 25 percent for men and from 8 to 24 percent for women. To achieve the target of universal access—or in Africa, 80 percent access by 2010—countries are considering new models, such as provider-initiated HIV testing and counseling (PITC), and adopting a mix of service delivery approaches, including integrated mobile and outreach services, family-based testing, door-to-door testing, couples testing, testing services for children, and national testing days.

The availability of HIV test kits and other commodities for HIV testing, together with a referral system that links clients to treatment, care, and prevention services where they can access essential medicines and commodities, is critical to success in scaling up access to HIV counseling and testing. The commodity management system must not only continue to meet the challenges of procuring and distributing ever-increasing quantities of HIV test kits and other supplies but also be able to deliver them to diverse service delivery points. However, reports from countries and programs indicate that commodity management systems for HIV counseling and testing are experiencing difficulties meeting the demand for scale-up. Although the HIV counseling and testing program manager's primary concern is strengthening the commodity management system to improve the availability and proper use of HIV testing commodities, the system that supplies medicines and commodities to the referral services must also work if the referral service is to function effectively.

<p style="text-align: center;">Scaling Up to Universal Access: Challenges for the Commodity Management System</p> <ul style="list-style-type: none">• To procure and supply ever-increasing quantities of HIV test kits and other supplies to keep pace with the rate of service expansion• To distribute adequate quantities of HIV testing commodities to increasing numbers of diverse service delivery points when they are needed
--

Commodity Availability Affects Demand for HIV Testing

Demand for HIV testing is influenced by several factors, including an individual's understanding of the importance of the service, and by incentives and disincentives for having an HIV test, such as perceived level of confidentiality of the service and options for treatment if the test is positive. Stock-outs of HIV test kits or other essential equipment such as syringes and needles to draw blood may require clients to return another day or go to another clinic. However, clients may be reluctant to spend time and expend resources to travel to a point of service where they may be turned away, and many clients who are turned away may not come back.

² WHO/UNAIDS/UNICEF. 2007. *Towards Universal Access: Scaling Up Priority HIV/AIDS Interventions in the Health Sector: Progress Report, April 2007*. Geneva: WHO.

HIV Counseling and Testing: Approaches and Service Delivery Models

VCT, also called client-initiated HIV counseling and testing

- Individuals actively seek HIV counseling and testing services.
- Emphasis is usually placed on individual risk assessment and management, the desirability and implications of taking an HIV test, return of results, and future options.
- Service delivery models and scenarios include—
 - Health facility-based/co-located
 - Stand-alone/freestanding facility outside health institutions
 - Integrated into existing services such as family planning clinics and harm-reduction clinics
 - Semi-mobile and mobile (outreach) services
 - National testing days and campaigns
- VCT may be offered at community-based locations and public, nongovernmental organizations (NGOs) or private for-profit facilities.

Provider-initiated HIV testing and counseling

- PITC is initiated by health care providers for clients attending health care facilities.
- Its main purpose is to offer medical and other services or to make specific clinical decisions.
- It is voluntary, and informed consent, counseling, and confidentiality are observed.
- Informed consent may be obtained using “opt-in” or “opt-out” approaches.
 - Opt in: Individuals request an HIV test or affirmatively agree to the test being performed.
 - Opt out: The provider recommends an HIV test, and individuals must specifically decline the test if they do not want it to be performed.
- In generalized epidemics,^a WHO recommends offering testing as part of the normal standard of care to all patients seen in a health facility. Depending on local circumstances, this may include offering testing at^b—
 - Medical inpatient and outpatient facilities, including tuberculosis (TB) clinics
 - Prenatal, childbirth, and postpartum health services
 - Sexually transmitted infection (STI) services
 - Health services for most-at-risk populations
 - Services for younger children (under 10 years of age)
 - Surgical services
 - Services for adolescents
 - Reproductive health services, including family planning
- In concentrated and low-level HIV epidemic settings, PITC may be offered at^b—
 - STI services
 - Health services for most-at-risk populations
 - Prenatal, childbirth, and postpartum services
 - TB clinics
- In all HIV epidemic types, WHO recommends that health care providers should recommend HIV testing as part of the standard of care to^b—
 - All adults, adolescents, or children who present to health facilities with signs, symptoms, or medical condition that could indicate HIV infection, for example, persons who have or are suspected to have TB
 - Infants born to HIV-positive women as a component of follow-up care
 - Children with suboptimal growth and malnutrition in generalized epidemic settings, and in other settings when malnourished children do not respond to appropriate nutritional therapy
 - Men seeking circumcision as an HIV-prevention intervention
- Service delivery models and scenarios—
 - Integrated into existing services such as hospitals, STI clinics, TB clinics, prenatal clinics, outpatient and inpatient clinics, reproductive health and family planning clinics
 - May be offered at public, NGO, or private for-profit facilities

a. WHO/UNAIDS define a generalized HIV epidemic as an epidemic where HIV is firmly established in the general population. HIV prevalence is consistently over 1 percent in pregnant women. WHO/UNAIDS. 2000. *Guidelines for Second Generation HIV Surveillance for HIV: The Next Decade*. Geneva: UNAIDS/WHO.

b. WHO/UNAIDS. 2007. *Guidance on Provider-Initiated HIV Testing and Counselling in Health Facilities*. Geneva: WHO.

Commodity Availability Affects the Quality of HIV Counseling and Testing Services

- Staff attitudes toward clients and service delivery may be negatively affected when the commodities they need to perform their job efficiently and safely are not consistently available, such as when staff must turn clients away repeatedly because of shortages of HIV test kits. Similarly, when gloves and sharps bins to safeguard staff and clients are not available, staff fears regarding infection control are affected, which in turn may exacerbate stigma at the point of service.
- After testing, some clients may not return to obtain their results. The availability of same-day testing through use of rapid test kits has been demonstrated to significantly increase the proportion of clients who receive their test results.
- For many clients, the lack of commodities such as HIV test kits can negatively affect their perception of the quality of the complete HIV testing service, including counseling. The reputation of the entire service is at stake if commodities are not available.

The availability of essential commodities for HIV testing and referral services is important for building and maintaining demand for HIV counseling and testing. Commodity management is the set of functions that makes this happen.

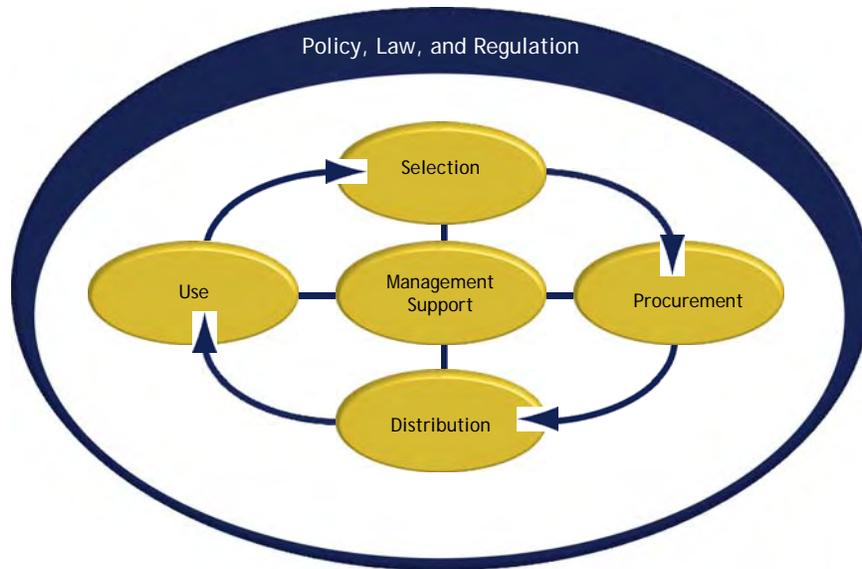
What Is Commodity Management?

Managing pharmaceuticals—medicines, diagnostics, vaccines, and other supplies—in any setting (public or private sector) and at any level (local, regional, or national) follows a well-recognized system that can be viewed as a cycle of **selection, procurement, distribution, and use** (Figure 1).

At the center of the cycle is **management support**. The functions of management support—financing, information management, human resources management, monitoring, and evaluation—hold the cycle together.

The entire cycle lies within a framework of **policy, law, and regulation** that establishes the mechanisms for each function and supports the pharmaceutical management system.

For the purposes of this document, the term “commodity management” is used in place of “pharmaceutical management” because this guide is primarily concerned with managing HIV testing commodities, equipment, and associated supplies. However, the concepts and principles are the same.



Source: Management Sciences for Health

Figure 1. Pharmaceutical Management Cycle

Every piece of the cycle must work well for the next step to occur effectively and efficiently. Problems in any part of the cycle can disrupt the whole commodity management system.

For example, if HIV test kit selection is not based on nationally approved and appropriately evaluated algorithms, procurement and distribution of inappropriate products will waste scarce resources, making necessary commodities unavailable. Similarly, it is difficult to encourage rational and appropriate use of HIV test kits and other commodities if shortages occur in first-line products as a result of poor procurement and distribution practices, such as inaccurate estimation of quantities needed or lack of transportation to distribute commodities where and when they are needed.

Strengthening national and local commodity management systems is important to ensure that commodities are available and appropriately used.

Commodities for HIV Counseling and Testing—More Than HIV Test Kits

Commodity requirements are largely determined by the service delivery model selected by planners and implementers and by available referral mechanisms. In particular, national- and program-level decision makers need to decide which interventions and services to include as part of their stand-alone VCT program.

This section provides a list of commodities that may be required for an HIV counseling and testing service. It also emphasizes the importance of having a commodity management plan for the HIV counseling and testing program and of taking a systematic approach to address the

commodity implications of establishing, managing, and scaling up HIV counseling and testing services.

Commodities needed for HIV counseling and testing may include—

- HIV test kits
- Automated analyzers, such as enzyme-linked immunosorbent assay (ELISA) readers
- Reagents and controls for ELISA testing (if appropriate to the quality assurance strategy)
- Equipment, reagents and hood for processing samples and conducting HIV-DNA or HIV-RNA polymerase chain reaction (PCR) testing for HIV diagnosis in infants
- Centrifuges
- Refrigerators
- Test-tube racks
- Timers
- Consumables, such as pipettes, pipette tips, and specimen tubes
- Supplies used to collect specimens, such as lancets, needles, syringes, and plasters
- Supplies and equipment to prepare, store, and transport, samples, such as dried blood spots (DBS) from infants, or for external quality assurance including filter paper cards, drying racks, low gas permeable bags, glassine paper for separating samples, desiccants, and humidity indicator cards
- Disposable gloves
- Disinfectants and cleaning supplies
- Sharps disposal bins for needles and lancets as defined under the Universal Precautions strategy
- Waste disposal (biohazard) bags for blood-contaminated materials, such as gauze, swabs, gloves, and testing cards
- Male and female condoms and water-based lubricants
- Tissues
- Safe drinking water and cups
- Television/video equipment and health education videos

- Information leaflets
- Office supplies for record keeping and stock management

Other commodities for HIV counseling and testing programs that provide comprehensive care or treatment services in line with national policies may include—

- Medicines to prevent HIV-related infections, such as co-trimoxazole prophylaxis
- Contraceptives
- Test kits and medicines to diagnose and treat STIs
- Medicines for palliative and supportive care, such as pain management
- Antiretroviral medicines for treatment and prevention of mother-to-child transmission (PMTCT)
- Laboratory equipment and supplies for diagnosing opportunistic infections, such as tuberculosis (TB)

STEPS IN MANAGING HIV COUNSELING AND TESTING COMMODITIES

Selection

The first step for national- and program-level planners and implementers is to map the various HIV counseling and testing service delivery models offered at the national or point-of-service level, or both, and to identify potential changes to the current mix based on the latest evidence and innovative practices. In addition, managers at the national and point-of-service levels will need to select the interventions and services to include in their HIV counseling and testing program based on the capacity of the point of service and the availability of referral services. For more information, refer to the Family Health International document, *Establishing Referral Networks for Comprehensive HIV Care in Low-Resource Settings*; see “Additional Resources” chapter for more details.

Steps in Selection

1. Consider the mix of service delivery models for HIV counseling and testing offered.
2. Develop or update national guidelines or algorithms for HIV testing.
3. Select the interventions to include in the program and list the commodities required.
4. Update the national and/or facility-level list(s) used to guide procurement.
5. Disseminate guidelines and update related materials.

Guidelines Required for Effective HIV Counseling and Testing Services

Standard guidelines or algorithms for HIV testing must be developed and regularly updated at the national level along with standard treatment guidelines for associated prevention, care, and treatment services that require medicines and other commodities. National and local guidelines should be developed or updated in accordance with international recommendations, and HIV testing guidelines should address the range of service delivery models to be used and the settings in which they will be deployed. Consequently, a country may have multiple HIV testing algorithms for different purposes and testing environments. Depending on the country context, the committees responsible for developing and updating the HIV testing algorithms and related standard treatment guidelines may need to work with the committees responsible for updating the lists used to guide procurement, such as the national essential medicines committee, to update the existing lists or formulary to reflect the needs of HIV programs. Also, in most countries, the HIV test kits selected will need to be registered by the national regulatory authority before they can be procured.

The benefits of standard algorithms and guidelines in relation to commodities include—

- More predictable demand for commodities, allowing for more accurate quantification (estimation of product requirements), thereby reducing shortages and waste
- Expert consensus on the most effective and economical product selection for a specific setting

- Defined basis on which to assess and compare quality of care

At the national level, important questions include—

- Have national guidelines or algorithms for HIV testing been developed? Are they current with international recommendations and product availability, and appropriate for the country context and service delivery models used or to be established?
- Do the guidelines or algorithms include recommendations for the identification and testing of infants and children? Are recommendations uniform across all existing program guidelines, for example, for HIV counseling and testing, PMTCT, and HIV-related care and treatment?
- Do the guidelines include recommendations for performing HIV testing in small-scale settings with limited resources in addition to testing at the central or hospital laboratory level?
- Are the guidelines available at all points of service that offer HIV counseling and testing in both the public and private sectors?
- Have the guidelines been distributed to donors to ensure that donor-financed procurement of HIV test kits is compatible with national guidelines?
- Have national standard treatment guidelines been developed and kept updated for related services, including prophylaxis and treatment of HIV-related diseases in both adults and children?
- Do the test kits, commodities, and medicines for HIV testing and related services need to be included on the national essential supplies or medicines list or formulary?

The next step at the point of service is to identify the national HIV testing guidelines, algorithms, or both, and the standard treatment guidelines that are relevant for the interventions to be offered. If national guidelines are lacking or inappropriate for local use, point-of-service-level guidelines in accordance with the national or internationally acceptable standards will need to be developed.

At the point of service, important questions include—

- If HIV testing will be performed at the point of service, what testing guidelines and algorithms will be used?
- Are national HIV testing guidelines and algorithms available and, if so, are they appropriate for the HIV counseling and testing context, service delivery model, and resources?
- For other planned interventions that require medicines and commodities (for example, co-trimoxazole preventive therapy), are national or local standard treatment guidelines available?

Evaluating and Selecting HIV Test Kits: The Process

The in-country selection of test kits and algorithms for HIV counseling and testing services is usually the responsibility of any or all of the following: the ministry of health (MoH), the national AIDS control program, and the national reference laboratory/institute. National evaluation of test kits is needed to establish which HIV tests are appropriate for the populations who are to be offered counseling and testing. Ideally, a national technical advisory group should be established to coordinate the review and evaluation of HIV test kits. The national reference laboratory or a recognized central laboratory is usually assigned overall responsibility for evaluating the accuracy and operational characteristics of HIV test kits in-country and determining the most appropriate combination and sequence of tests. It is important that the evaluation process allows point-of-service-level staff that will be using the test kits to contribute to the development of criteria for selecting tests and to decision making on the algorithm to be adopted. Practical guidance for developing country-specific protocols for evaluating HIV testing technologies in Africa is available,³ and WHO evaluations of performance and major operational characteristics of commercially available rapid tests can be used by countries to select products to include in the evaluation.⁴

The international market for rapid HIV test kits is dynamic and evolving. The availability of cheaper, faster-acting HIV test kits that are simpler to use and test specimens that are easier to collect, such as saliva, is on the increase. Products are also removed from the market for a number of reasons, for example, as demand drops when the technology is superseded by newer products. Countries and program managers are likely to face increasing pressure from manufacturers and suppliers to adopt new testing technologies as they scale up their programs. However, evaluating new test kits and algorithms requires financial and technical resources, and the costs incurred in implementing the changes include updating, printing and disseminating guidelines and record and reporting forms, and retraining of staff, among others. Although manufacturers or suppliers can be asked to bear the cost of evaluating test kits, countries or programs may subsequently find themselves under pressure to adopt a test kit that has shown only a marginal benefit. WHO and the U.S. Centers for Disease Control and Prevention (CDC) advise that program planners should assess the potential advantage of a new test before proceeding with a formal evaluation.⁵

Important questions include⁶—

- Does the evidence from published studies indicate that the test has greatly improved performance characteristics?

³ WHO/CDC/Association of Public Health Laboratories. 2003. *Guidelines for Appropriate Evaluations of HIV Testing Technologies in Africa*. Atlanta: CDC. Available from http://www.who.int/diagnostics_laboratory/publications/guidance/en/index.html.

⁴ WHO/UNAIDS. 2004. *HIV Assays: Operational Characteristics (Phase 1) Simple/Rapid Tests. Report 14*. Geneva: WHO/UNAIDS. http://www.who.int/diagnostics_laboratory/evaluations/hiv/en/index.html.

⁵ WHO/CDC/Association of Public Health Laboratories. 2003. *Guidelines for Appropriate Evaluations of HIV Testing Technologies in Africa*.

⁶ Ibid.

- Is the test simpler to perform?
- Does the test have a longer shelf life, or is it more stable to transport and store?
- Are significantly reduced costs associated with adopting the test kit, such as lower price per test, reduced costs of consumables, or less wastage, and will these savings be maintained in the long term?

Countries and programs may also need to revise or add alternative HIV testing algorithms to support new service delivery models such as mobile testing and to address the needs of children. Planners should develop a comprehensive budget for evaluating new tests and updating algorithms that includes requirements for technical assistance. The supply management considerations for implementing changes to national HIV testing algorithms to support scale-up are discussed in the chapter “Commodity Management Considerations for Implementing Changes to National HIV Testing Guidelines.”

Factors to Consider When Selecting HIV Test Kits

Sensitivity and specificity of the test—The *sensitivity* of a test is the probability of a positive test in people infected with HIV, expressed as a percentage. The *specificity* of a test is the probability of testing negative in people infected with HIV, expressed as a percentage. WHO and UNAIDS recommend that HIV rapid tests should have a *sensitivity* greater than 99 percent, and a *specificity* greater than 98 percent.⁷ The reproducibility of the test and inter-reader variability are also important considerations.

HIV variants and subgroups—Most rapid tests detect antibodies to both HIV-1 and HIV-2. However, part of the in-country evaluation should include ensuring that test kits detect the HIV variants and subgroups present in the population tested.

Time taken to generate a result—Minimizing turnaround time means that more clients are likely to learn their test result. Most HIV rapid tests provide a result within 10 to 30 minutes.

Simplicity of use—The ability to generate valid and reliable results depends on—

- Ease of the procedure and the technical training required to perform the test.
- Number of steps to be performed between collecting the sample and interpreting the results.
- Ease of interpretation of the test results. Rapid HIV tests with stable end-reading points that can be interpreted visually without equipment are preferred.
- Inclusion of an internal control to validate the results.

⁷ WHO/UNAIDS. 2007. *Guidance on Provider-Initiated HIV Testing and Counselling in Health Facilities*. Geneva: WHO.

WHO/UNAIDS assign a rating on ease of performance as part of their evaluation of rapid HIV test kits. Tests are rated as very easy, easy, or less easy.⁸

It is critical to select HIV test kits that are appropriate for the local capacity—language, training, and skills—of the technical staff who will use them and the setting in which they are to be used.

Laboratory infrastructure—Requirements for constant electricity or water supply and maintenance of equipment and spare parts can be problematic in geographically remote areas.

Equipment and consumables needed to perform the test—Additional equipment, reagents, and supplies can add considerably to the cost of testing and make supply management more complex.

Specimen type—Tests that use whole blood from a finger-prick sample rather than plasma or serum make collection easier and safer, and eliminate the need for centrifuging samples.

Storage—The need for refrigeration or cold storage of test kits or associated consumables are important considerations, particularly for bulky items and for tests that are to be used in remote areas where the power supply may be erratic. For rapid HIV tests, the stability and shelf life at “room” temperatures at local storage and service delivery points, such as mobile units, where temperatures may range between 8 and 30 degrees Celsius may need to be evaluated.

Packaging—Many HIV test kits are manufactured with short shelf lives of 18 months or less. In low-volume settings, rapid HIV test kits that are packaged in small pack sizes or that can be distributed singly enable points-of-service to order quantities that reflect the number of tests that can actually be used before the pack expires. Large pack sizes of tests that cannot be distributed singly, for example, because only one internal control is included to validate results for the entire pack, are especially problematic for HIV test kits that are being considered for use as tiebreakers.

Shelf life, availability, quality, and cost—The anticipated shelf life of the product on arrival in country, regular availability from the supplier, product quality, and total cost per test are also important criteria. In general, rapid HIV test kits that are manufactured with a shelf life of 12 months or longer are preferred.

Factors to Consider in Determining a Testing Strategy and Testing Algorithms

In developing an HIV testing strategy and choosing algorithms, the following factors should be considered—

- Expected HIV prevalence
- Laboratory infrastructure
- Anticipated client flow

⁸ WHO/UNAIDS. 2004. *HIV Assays: Operational Characteristics (Phase 1) Simple/Rapid Tests. Report 14*. Geneva: WHO/UNAIDS. http://www.who.int/diagnostics_laboratory/evaluations/hiv/en/index.html.

- Availability of refrigerators or regular electricity supply
- Impact of the protocol on the delivery of health services (for example, same-day testing versus return appointments)
- Cost
- Performance of the test kits (in terms of sensitivity and specificity) in the settings in which they will be used
- The mix of HIV counseling and testing service delivery approaches to be used

Testing protocols are designed to maximize both sensitivity and specificity for HIV antibody detection. Several international organizations such as the WHO and the CDC currently provide in-country technical assistance to countries to help them develop, review, and evaluate national HIV testing guidelines or algorithms, including HIV test kit selection. Please see the “Additional Resources” chapter for more information.

Serial versus parallel testing—Testing algorithms that use rapid test technologies can incorporate either serial or parallel testing. In serial testing, all persons are tested with a rapid HIV test. If the test is positive, a second, different rapid HIV test that uses a different antigen or testing principle is performed. In low-prevalence settings with an HIV prevalence of less than 5 percent, a third confirmatory test may be required.⁹ The tests are performed *in series*, one after the other, as needed. In parallel testing, all persons are tested using two tests simultaneously (*in parallel*). Parallel testing is recommended only when testing whole blood finger-stick samples and not venous blood. For discordant test results in both approaches, and depending on the setting, a sample can either be sent to a referral laboratory or be tested further with a third type of rapid HIV test.

The advantages and disadvantages of serial and parallel testing are outlined in Table 1. WHO and UNAIDS recommend serial testing in most settings because it is less expensive.¹⁰ The decision to use serial or parallel testing should be based on available scientific evidence, performance of the tests selected, performance of the testing laboratory or point of service, implications for supply management, and cost of the alternative algorithms.

⁹ WHO/UNAIDS. 2007. *Guidance on Provider-Initiated HIV Testing and Counselling in Health Facilities*. Geneva: WHO.

¹⁰ *Ibid.*

Table 1. Serial versus Parallel Testing Strategies

Testing Strategy	Advantages	Disadvantages
Serial testing	<ul style="list-style-type: none"> • Less expensive because fewer second (confirmatory) tests are required. • Requires less storage space. 	<ul style="list-style-type: none"> • Longer waiting time for persons who test positive on the first test. • If finger-prick sample testing is used, a second sample must be collected if the first test is positive.
Parallel testing	<ul style="list-style-type: none"> • Clients may perceive that two tests are better than one; increased trust in the result can reduce the number of clients seeking retesting. • No waiting time for result of confirmatory test. 	<ul style="list-style-type: none"> • More expensive, especially in low-prevalence settings, because more second (confirmatory) tests are required. • Both first and second tests must be continuously available for HIV counseling and testing services to be offered. • More storage space is needed for second (confirmatory) test kits.

Selecting Technologies for Early HIV Diagnosis in Infants and Children

Because of the persistence of maternal HIV antibody in children born to HIV-infected mothers, a positive antibody test in children under 18 months does not necessarily mean that the infant is infected with HIV. As countries move forward with initiatives to diagnose and provide treatment to HIV-infected infants and children at earlier ages, approaches for improving access to virological testing are being explored and expanded. Because virological testing technologies are rapidly evolving, becoming faster and more automated, and prices are constantly decreasing, decision makers are referred to websites and resources in the “Additional Resources” chapter for more detailed information.

Nucleic acid detection technologies—These include HIV-DNA PCR tests, which are usually qualitative and currently most widely used for HIV diagnosis in infants, and HIV-RNA PCR and other nucleic acid detection techniques. HIV-RNA techniques also provide quantitative information and can be used for monitoring the response to antiretroviral therapy and possibly identifying treatment failure. Both DNA and RNA PCR technologies are expensive and complex to use, requiring dedicated equipment, space, and skilled staff.¹¹

Ultrasensitive p24 antigen detection—Although this ELISA-based technology is less expensive than other nucleic acid technologies, at the time of writing this document, the equipment and most of the reliable consumables are not commercially available together.¹²

¹¹ WHO. 2007. *Early Detection of HIV Infection in Infants and Children: Guidance Note on the Selection of Technology for Early Diagnosis of HIV in Infants and Children*.

http://www.who.int/hiv/paediatric/EarlydiagnostictestingforHIVVer_Final_May07.pdf.

¹² Ibid.

Dried blood or plasma spots—DBS on filter paper can be used for some DNA and RNA PCR technologies. DBS obtained from a heel- or toe-prick sample are dried and then can be shipped to central locations for testing.

WHO advises that the key considerations for selecting technologies include¹³—

- Commercial availability and cost of equipment, reagents, and consumables
- Location of the testing facilities; for example, appropriateness of the technology for settings where testing is centralized and specimens transported from other regions of the country for processing
- Workload and sample throughput, including consideration of the projected number of tests to be processed in the longer term (2 to 5 years)
- Sample collection and transportation, including the use of DBS where transport and refrigeration are problematic
- Laboratory facilities and infrastructure, including refrigeration and freezer capacity and systems and procedures for quality management
- Training and availability of laboratory staff
- Requirements and availability of training and specialized preventive maintenance and repair
- Expected shelf life of consumables on delivery and shelf life once the reagent or package of filter papers is opened
- Use of the equipment for other purposes, for example, detection of hepatitis B or C and STIs

WHO, CDC, and other U.S. government partners can provide technical guidance on selecting technologies for virological testing. WHO may be able to assist in the purchase of equipment at reduced prices through the WHO Bulk Procurement Scheme.¹⁴

Required HIV Test Kits, Equipment, Supplies, and Medicines

The next step in selection is to make a list of all the commodities and supplies required for delivering HIV counseling and testing services. List equipment separately. At the point-of-service level, follow the national or local guidelines where they are available and appropriate. Also consider the following questions—

¹³ Ibid.

¹⁴ Information on the WHO Bulk Procurement Scheme is available at http://www.who.int/diagnostics_laboratory/en/. Follow the links to Bulk Procurement Scheme.

- What equipment, testing kits, reagents, consumables, and specimen collection supplies are needed to perform HIV tests? Will timers be needed for HIV test kits that require precision timing to generate an accurate result?
- Does the equipment require unique commercial brands of testing reagents or kit? Does the equipment need specialized preventive maintenance and repair? Are the parts accessible? Will a separate service agreement be needed?
- Are refrigerators needed to store test kits, blood samples, or commodities? Is a regular source of electricity or a reliable backup generator available to run refrigerators and equipment?
- What supplies are needed to safeguard the health and safety of the staff performing HIV testing?
- What other commodities and supplies, such as condoms and information leaflets, will be given out as part of the service?
- Will the services offered require medicines or diagnostic kits, for example, to diagnose STIs? What medicines and commodities will be needed, and what supplies—such as tablet bottles, labels, and information leaflets—will be needed to dispense or use them safely? Do staff have the legal authority to dispense medications?

When lists of all the commodities and equipment have been made, decide if each item (together with its essential accessories) is vital, essential, or nonessential. This is called a *VEN* analysis.

V—*Vital* items are those the provider cannot work without, such as specimen collection equipment for HIV testing.

E—*Essential* items are those the provider would normally always have, such as sharps containers.

N—*Nonessential* items are those that are good to have but that can be done without. In HIV testing, an example would be videos for health education.

A *VEN* analysis should be used to decide how to allocate budget funds if not enough funds are available to pay for everything; it can also be used to establish priorities for procurement and stock monitoring if storage space or staff time is limited.

The commodity and equipment lists, indicating the *VEN* category for each item, can now be shared with the staff responsible for program implementation and procurement. As mentioned previously, at the national level the list of essential supplies used to guide procurement of laboratory reagents and supplies will need to be updated where it exists. If medicines are to be included in the package of services, it will also be important to ensure that the medicines needed are included in the national essential medicines list or formulary.

Disseminating Algorithms and Guidelines

The printing and dissemination of algorithms and guidelines for HIV counseling and testing is an important yet very often neglected last step. When planning for the revision and update of HIV testing algorithms and guidelines, it is important to identify and secure adequate funding to ensure that sufficient copies are printed and distributed to all the points of service and staff responsible for performing HIV testing in both the public and the private sectors. In addition, organizations and donors that provide support to HIV counseling and testing programs, particularly those that procure commodities and supplies, need to be informed of proposed changes early on.

Confusion over HIV Testing Algorithms Can Affect Supply Management

In one country, a parallel HIV testing algorithm using Determine™ HIV-1/2 and Uni-Gold™ HIV has been adopted for HIV counseling and testing. In 2006, program managers investigating causes of stock-outs—and particularly why some testing sites were continually reporting stock-outs of Determine™ HIV-1/2 together with surpluses of Uni-Gold™—discovered that one of several contributing factors was confusion among point-of-service-level staff over whether to use serial or parallel testing for HIV counseling and testing. Strategies to raise awareness on national HIV testing algorithms, including training and posting job aids that detail national testing algorithms at testing sites, are reported to have resolved the problem.

Source: MSH/RPM Plus.

The dissemination of new or revised guidelines needs to be coordinated with the update of associated materials, such as curricula and training materials, standard operating procedures (SOPs) and manuals for laboratories and points of service, supply management forms, job aids, and reporting and recording forms. The supply management considerations for implementing changes to national HIV testing algorithms to support scale-up are discussed further in the chapter “Commodity Management Considerations for Implementing Changes to National HIV Testing Guidelines.”

Procurement

Managing Procurement for HIV Counseling and Testing Services

In recent years, national governments and program managers have substantially scaled up HIV counseling and testing programs and diversified service delivery models. Although the situation varies from country to country, procurement and distribution systems have often struggled to keep up with expansion. The chapter “Commodity Management for Taking HIV Counseling and Testing Programs to Scale” discusses some of the underlying causes and outlines approaches based on country experiences to build capacity in the commodity management system for going to scale. More information is available in the “Additional Resources” chapter.

In many countries, national governments and their partners are now working to coordinate and rationalize multiple vertical supply systems that were set up as short-term fixes to enable HIV counseling and testing programs to pilot and expand services. Fragmented procurement systems in which HIV test kits are procured by the national government, two or more bilateral donors, and multiple international NGOs together with a donation program are not unusual.

Steps in Procurement

1. Estimate how much of each product is needed and reconcile needs with available funds in coordination with other programs and donors.
2. Select procurement method.
3. Choose suppliers.
4. Specify contract terms.
5. Monitor order status and supplier performance.
6. Receive and check products and make payments.

At the service delivery level, a single facility may end up receiving HIV test kits through three or more different supply mechanisms, for example, for PMTCT, the TB clinic, and the VCT center.

Before setting up a new procurement and supply mechanism for HIV testing commodities and supplies, consider the following questions—

- What mechanisms for procuring HIV test kits and supplies currently exist at the national and point-of-service levels?
 - What constraints are there to using an existing supply mechanism? Can agreements be put in place to transfer funds to the organization or department currently responsible for procurement and procedures established to account for expenditures?
-
- Does the existing procurement mechanism have the capacity to supply your program or department? Can resources be pooled to strengthen the capacity of the existing system for going to scale?
 - If no system exists, can procurement be integrated into the existing medicine or laboratory supply system?
 - If the procurement of HIV test kits is to be decentralized to lower levels, do the staff have the skills, finances, managerial support, and information to carry out procurement functions successfully?
 - At the facility level, can supply management for the departments and clinics offering HIV counseling and testing be consolidated? Can the process for managing discordant results be centralized at the facility to minimize wastage of tiebreaker tests?

Quantification—Estimating Quantities of Commodities Needed

The first step in procurement is deciding how much of each commodity to buy. The principles for estimating requirements are the same at the national and point-of-service levels. Because many rapid HIV test kits arrive in-country with a shelf life of 18 months or less, the central and point-of-service-level staff responsible for quantification will need to calculate requirements for smaller and more frequent shipments. The availability of cold or refrigerated storage may also restrict the amount of stock that can be held at any one time. Quantifying needs for HIV test kits and other commodities in countries that are scaling up their programs is complex. Country experiences show that actual need generally exceeds projected needs and that inaccurate quantification is usually a result of several interrelated problems. Some of the challenges identified are presented in the following box.

Challenges Reported to Constrain Accurate Quantification of HIV Test Kits at the National Level

- Management information systems are too fragmented or weak to supply timely, reliable, and accurate data for national or programwide quantification.
- Programs experience so many stock-outs that estimating future needs from consumption data with any degree of accuracy is difficult. In many countries, available funding limits the quantities that can be procured, leading to frequent stock-outs.
- When quantification is based on service delivery data, that is, the number of persons tested, consumption is underestimated where repeat tests, wastage, or tests used for quality control or training are not recorded in the registers.
- The rate of scale-up is not constant and can fluctuate enormously, making estimation of future commodity requirements difficult. The opening of new sites is not always well coordinated with supply management, and staff responsible for quantification are not always kept informed of plans to open new sites, run promotional campaigns, or expand service delivery options.
- Point-of-service staff lack skills to accurately calculate quantities of products to order from the central distribution system. In systems where shortages occur frequently at the central level, staff can be tempted to hoard supplies. The consequent over or underordering by facilities contributes to inaccurate quantification at the national level.
- The same HIV test kits can be used for multiple purposes—diagnosis, screening of blood, surveillance—and in different service delivery settings. The kits very often come through different supply channels, and when kits run short in one program, for example a PMTCT donation program, supplies can be diverted from their intended use to fill the gap. Poor record keeping of loans given or received ultimately leads to inaccuracies in calculating consumption for each supply stream.
- As discussed in the section on selection, if point-of-service staff do not follow standard testing algorithms, including recommendations on order of use and parallel versus serial testing, stock-outs and wastage can result where quantification at the central level is based on the use of standard testing guidelines.

Source: MSH/RPM Plus.

Successful quantification for HIV counseling and testing programs that are scaling up requires good coordination, communication, and team work. Several countries have established a national committee or working group responsible for coordinating procurement and quantification of commodities, including those for HIV counseling and testing programs. The roles and responsibilities of coordinating bodies at both the country and point-of-service levels are discussed further in the chapter “Commodity Management for Taking HIV Counseling and Testing Programs to Scale.” With regard to quantification, the responsibilities of the coordinating body should include—

- Coordinating the development of one-to-two-year forecasts of commodity needs to inform resource mobilization so that scale-up is not stalled by inadequate funding for procurement of HIV test kits and other commodities.
- Regularly reviewing actual consumption of HIV testing commodities and rate of scale-up of services and adjusting procurement quantities accordingly.

- Ensuring that staff responsible for quantifying needs and developing procurement plans are kept informed of plans to change standard testing guidelines, open new points of service, run promotional campaigns, or expand service delivery options.

Accurate and timely consumption and inventory data are required at all levels to estimate future needs reliably. For a centralized procurement system, building an effective management information system to gather and verify data from districts, NGOs, and diverse service delivery points is an essential investment for going to scale. At the point-of-service level, improving quantification skills of staff responsible for commodity management and record-keeping practices is key to minimizing stock-outs and wastage. Management information systems are discussed in more detail in the chapter “Issues to Consider for Commodity Management for HIV Counseling and Testing Programs.”

A program’s needs can be quantified in several ways, including—

Consumption or usage method—Uses data on past consumption or quantity used.

- When reliable data are adjusted for stock-outs and projected changes in use, this method gives the most accurate projection of future needs.
- This method is especially useful for large, well-established supply systems.
- To be reliable, the system must have a relatively uninterrupted supply and reliable inventory record keeping (see Distribution section for more details).
- This method assumes products are used rationally; the disadvantage is that it can perpetuate irrational use.
- This method predicts future needs most accurately when current usage patterns will continue. However, the average rate of increase (or decrease) in consumption of products over the period reviewed can be used to develop assumptions about future program expansion.

Morbidity method—Uses standard testing or treatment guidelines to estimate the need for specific products on the basis of the expected number of client visits to points of service and the prevalence or incidence of diseases. This method uses HIV prevalence to estimate the need for HIV test kits and is useful for estimating needs for new programs or new service delivery approaches. Alternatively, data on service delivery, that is, the actual number of persons tested over a period of time, and standard testing or treatment guidelines can be used to project future needs for a program or a point of service. Service delivery data can also be used to set targets based on the estimated number of people to whom a program or point of service can offer HIV testing in a defined period given the available resources.

Proxy consumption or proxy usage method—Data from other points of service, regions, or countries are adjusted or extrapolated to the specific situation on the basis of population coverage or service level to be provided. This method can be used when data for using the other methods are deemed unreliable.

General Principles of Quantification

- Use at least two quantification methods to check your estimates.
- When quantifying needs for a new service or intervention, order extra supplies to “fill the pipeline” (e.g., for filling up shelves at each level in the supply chain and at each facility).
- Quantification will need to consider “lead time”—the average time between recognizing that a commodity needs to be ordered to having it available for use. The longer the lead time is, the more safety or buffer stock will be needed to prevent stock-outs between orders.
- Adjust quantification estimates for losses or waste, and take into account the amount of products already in the system.
- No matter which method is used, a gap often exists between estimated needs and available funds, requiring decisions to be made on how to adjust and reconcile the quantities needed. Consider splitting the shipments if all the funds are not available at the time of placing the order. The VEN analysis will help prioritize what to buy, and the quantification process may help justify an increase in funding or a higher budget when applying to donors.

Tools available to assist planners and managers to quantify needs of rapid HIV test kits and other commodities include—

- **Guide for Quantifying HIV Test Requirements**—a manual developed by John Snow, Inc., for the DELIVER project funded by the U.S. Agency for International Development (USAID) that helps program managers and procurement staff select recognized methodologies for quantifying HIV test requirements in developing-country settings and apply them based on specific country circumstances.¹⁵
- **ProQ: Quantification Software for HIV Tests**—a software tool developed by John Snow, Inc., for the USAID-funded DELIVER project that quantifies HIV test requirements based on realistic forecast demand, assessment of existing supply chain capacity, and availability of resources for procurement.¹⁶
- **Quantimed**—an electronic tool developed by MSH for the USAID-funded Rational Pharmaceutical Management Plus (RPM Plus) Program to assist health planners and program managers determine quantities of medicines and supplies, including HIV test kits, required for a program and to assist in planning and budgeting.¹⁷

Examples of how to quantify HIV test kits at the point-of-service level are given in Annex A.

¹⁵ Y. Chandani, L. Teclemariam, D. Alt, C. Allers, and L. Lyons. 2006. *Guide for Quantifying HIV Test Requirements*. Arlington, VA: DELIVER for the U.S. Agency for International Development.

¹⁶ To request a copy of the ProQ CD, e-mail deliver_pubs@jsi.com.

¹⁷ To request a copy of the *Quantimed* CD and manual, e-mail Quantimed@msh.org.

Where Will Commodities Be Procured?

At the national level, a priority for the national committee or working group responsible for coordinating procurement is developing a procurement and distribution plan to support the planned scale-up of HIV counseling and testing. In addition to developing the one-to-two-year forecasts of commodity needs discussed previously that will inform resource mobilization, an important first step is mapping the roles of all stakeholders and partners currently funding, procuring, or supplying commodities to HIV counseling and testing programs or who plan to do so. The coordinating group can then build on the relative strengths of its members and partners to prepare a procurement plan that avoids gaps and duplication. The plan synchronizes the various procurement mechanisms and delivery schedules to ensure the availability of all the HIV test kits and associated supplies that are needed to perform HIV testing. The plan needs to be updated regularly to reflect the inputs of new partners and to adjust procurement and distribution quantities and schedules where scale-up of HIV counseling and testing programs proceeds faster or slower than expected.

When selecting a procurement method, the key considerations are market availability, quantity required, required delivery date, and procurement regulations of the procuring institution. Although significant savings can be made in tendering for commodities, particularly on the international market and when buying in bulk, procurement methods for HIV test kits are restricted by the availability of these products, which usually have only limited or single sources. Direct contracting with a supplier for a period of repeat supply, limited international bidding restricted to a number of qualified suppliers, and procurement from a not-for-profit supplier or UN agency are the methods typically used at the national level. Shopping—where price quotes are compared from usually three suppliers—is a method frequently used for procuring supplies at the point-of-service level from local sources or for emergency orders at all levels. Procurement managers may need to apply for special exemptions for HIV test kits and related commodities where national procurement regulations require international (or national) competitive bidding. Similarly, where donor-specific preconditions and procurement procedures will result in long delays before orders for HIV testing commodities can be placed, program managers may need to negotiate with donors to streamline procedures.

HIV testing commodities can be obtained from various sources—

- The product manufacturer
- UN agencies supplying HIV test kits that have been evaluated by WHO and found to meet WHO-accepted standards
 - The WHO Bulk Procurement Scheme¹⁸ accepts orders from WHO programs, UN agencies, WHO member states, NGOs with official relations with WHO, and other clients such as donor-supported projects and regulatory bodies.

¹⁸ Information on the WHO Bulk Procurement Scheme is available at http://www.who.int/diagnostics_laboratory/en/. Follow the links to Bulk Procurement Scheme.

- UNICEF Procurement Services¹⁹ undertakes procurement on behalf of governments, NGOs, UN agencies, international financial institutions, philanthropic organizations, and universities.
- United Nations Population Fund (UNFPA) Procurement Services²⁰ accepts orders from UN agencies, funds, and programs; developing-country governments; NGOs; international funding organizations; and institutions.
- An international procurement agent or supplier
- Government stores or the central laboratory
- Private pharmacies or wholesalers
- Nonprofit or low-cost international or local suppliers
- Local shops or markets
- Donors and their implementing agencies: for example, funded by the U.S. government as part of PEPFAR, the SCMS project supplies PEPFAR-supported projects and implementing partners with HIV medicines and other commodities and can supply projects supported by national governments and other donors subject to individual arrangements²¹
- Companies that coordinate applications for and distribution of donations, such as the Axios Foundation,²² which coordinates donations of Determine™ HIV-1/2

Procurement staff may need assistance in obtaining information about sources and prices of HIV test kits and other products both locally and on the international market, in constructing procurement bids, and in developing contract terms. Using strict criteria when constructing procurement bids is important to prevent frequent product changes and ensure continuity.

Documents that contain regularly updated information on sources and prices of HIV test kits include—

- **International Drug Price Indicator Guide** (2007 edition) published by MSH in collaboration with WHO is updated annually.²³
- **HIV Test Kits Listed in the USAID Source and Origin Waiver: Procurement Information Document** (4th edition, August 2008) is updated annually by MSH/RPM Plus.²⁴

¹⁹ Information on UNICEF Procurement Services is available at <http://www.unicef.org/supply/>.

²⁰ Information on UNFPA Procurement Services is available at <http://www.unfpa.org/procurement/>.

²¹ Information on the SCMS project is available at <http://scms.pfscm.org>.

²² More information on Axios and the donation programs the foundation manages can be accessed at <http://www.axios-group.com/en/>.

²³ Available online at <http://www.msh.org>.

- **Sources and Prices of Selected Medicines and Diagnostics for People Living with HIV/AIDS** (6th edition, June 2005)²⁵ is a publication of UNICEF, UNAIDS, WHO, and Médecins Sans Frontières.

Considerations when choosing sources of HIV testing commodities are—

- **Quality of products and service**
 - Quality is the primary consideration and must not be compromised by pricing or any other factor.
 - Procurement should be restricted to HIV test kits that are registered in-country or that can be registered easily and quickly where systems to register technologies such as HIV test kits exist and function.
 - Use recognized and trusted suppliers who supply good-quality products and operate reliable services.
 - For bulk procurement at the national level, prequalification of suppliers is especially useful to facilitate quality assurance and service. WHO evaluations of performance and major operational characteristics of commercially available rapid tests can be used to verify claims about quality.
 - For procurement using funds from the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), countries are required to adhere to Global Fund policies on procurement and supply management, which emphasize the purchase of products that have been prequalified by WHO (or that have been produced according to Good Manufacturing Practices [GMP]).²⁶
 - At the point-of-service level, exchange experiences with other program providers and procurement staff to identify reliable sources.
 - For equipment, initial training in the use of the equipment, including routine equipment maintenance, technical support by the supplier, regularly scheduled preventive maintenance, and emergency repair, and the availability of spare parts will all need to be considered. Experiences of other programs can be helpful in verifying supplier performance, particularly with regard to response times for emergency repairs.

²⁴ Available online at <http://www.msh.org/projects/rpmpplus/WhatWeDo/HIV-AIDS/Test-Kits-Procurement.cfm>.

²⁵ Available online at <http://www.unicef.org/supply/files/sourcesandprices2005.pdf>.

²⁶ More information on Global Fund quality assurance policies for procurement of pharmaceutical products can be accessed at <http://www.theglobalfund.org/en/>.

- **Competitive price**
 - Use the lists of indicative prices discussed previously to initiate price negotiations. Price reductions can usually be negotiated for bulk purchases or regular repeat orders.
 - Where order volumes at individual points of service or programs are insufficient to achieve price reductions, pooled procurement at the national or regional level can be used to reduce prices. However, experience from essential medicines has shown that to obtain best prices, guaranteed timely payments and international competition are needed together with procurement capacity to manage the process and assure product quality. Harmonization of algorithms and packaging requirements across programs is an important step in facilitating pooled procurement.
 - Some companies will sell their products at significantly reduced prices for programs in selected resource-limited countries. To access these differential pricing agreements, procurement staff may need to work with program managers to set up safeguards to ensure that these products do not leak into countries not covered by the agreement. CHAI has negotiated special pricing for selected rapid HIV test kits for CHAI Procurement Consortium Member Purchasers. Member Purchasers may include ministries of health or NGOs supporting national care and treatment programs.²⁷
 - At the point-of-service level, when comparing prices of different suppliers, consider hidden costs such as transport, delivery times, custom duties, and taxes.
- **Shelf life**
 - Given the short shelf lives of most HIV test kits, an important consideration when selecting a supplier is the minimum remaining shelf life that the product will have when it is delivered to the country or point of service.
- **Delivery time and scheduling**
 - Using suppliers with long or unreliable delivery times can present problems and may require extra storage space and tie up funding in safety stock. Long delivery times and increased stock holding also increase the risk of stock-outs or waste when scaling up occurs faster or slower than planned.
 - For commodities such as HIV test kits that are manufactured with a short shelf life and often require refrigerated or cool storage, the requirement for minimum shipping quantities can be problematic. Suppliers that agree to supply more recently manufactured stock and to schedule deliveries of smaller quantities more frequently and at a reasonable cost to reduce storage space needs are preferred.

²⁷ More information on CHAI and the CHAI Procurement Consortium can be accessed at <http://www.clintonfoundation.org>.

- **Value-added services**
 - Some manufacturers will provide training and additional commodities as part of a competitive package; however, it is important to ensure that none of the factors listed previously is unduly compromised for additional services.

Program managers need to work with procurement staff to develop procurement contracts that allow procurement to be flexible and responsive to fluctuations in scaling up HIV counseling and testing services and to ensure that contracts address the issues that are unique to HIV testing technologies. Contracts should include staggered deliveries and ideally allow adjustments to order quantities should scale-up go faster or slower than expected. Minimum acceptable shelf life on delivery should be specified in the contract or stamped on the purchase order. Any negotiated package of training, technical support, or maintenance and emergency repair for equipment should be detailed. As mentioned earlier, the market for rapid HIV test kits is rapidly evolving, with cheaper, faster-acting technologies that are simpler to use and test specimens that are easier to collect continually coming onto the market and decreasing prices on existing products. Consequently, program managers need to consider whether long-term contracts that achieve lower prices in the short term could restrict their programs from benefiting from substantial price reductions and improved products in the long term.

The team responsible for coordinating scale-up of HIV counseling and testing services should work closely with procurement staff to monitor order status and adjust scale-up plans as needed to manage unanticipated events, such as extended lead time caused by production difficulties. Keeping records of supplier performance is helpful to inform future selection of sources.

Donations: The Good, the Bad, and the Ugly

Donations of HIV testing commodities such as HIV test kits can help underfunded programs and have been beneficial in helping many countries to scale up their HIV counseling and testing programs. But donations can also cause unanticipated problems if they are not carefully controlled and if the donor does not understand the needs of the recipient country or program.

Donated HIV testing commodities may be incompatible with existing standard testing guidelines and systems and may compromise the quality of the program. In the absence of country-specific guidelines or policies, WHO guidelines for drug donations (revised in 1999) can assist program managers in making decisions regarding medicine and commodity donations. As mentioned earlier, many rapid HIV test kits have a short shelf life from the date of production. As a consequence, programs or points of service can be burdened with managing the destruction of outdated test kits if needs are poorly forecast. In addition, lack of continuity of donor support for HIV test kit procurement can affect the quality of HIV counseling and testing services provided.

Significant program costs may be incurred in accepting donations, including—

- Fee paid to the national regulatory authority to register the medicine or commodity
- Customs duties, taxes, and tariffs
- Storage and distribution costs
- Costs of establishing and managing a parallel information system to track products and to collect, analyze, and report data for renewal applications
- Cost of relabeling in the local language
- Cost of retraining staff to use the donation
- Cost of expensive reagents or equipment needed to use the donation

Where resupply requires the country or program manager to report data to verify that the donated product has been used according to the terms of the donation program, problems result when the existing management information system lacks the capacity to produce the necessary information in the time needed. Stock-outs in donation programs, for example for PMTCT, are not uncommon and affect other HIV counseling and testing services when test kits are diverted from their intended use to fill the gap as managers work to renew the application. Procedures to verify the quality of the data submitted are generally lacking. In some countries, scarce local resources

are used to set up parallel systems to store and deliver products to points of service and to collect and report data required to maintain the donation program.

Communicating needs to donors and letting them know about successes and failures resulting from their donations are important. Consider doing the following—

- Send donors copies of standard testing or treatment guidelines, and use the VEN analysis and quantification process to let donors know what and how much is needed.
- Invite donors and their implementing agencies to communicate with or join the national committee or working group responsible for coordinating procurement and quantification of HIV testing commodities to ensure that quantities donated and delivery schedules are preplanned to avoid duplication or gaps and that problems are identified and dealt with early.
- Clarify who will be responsible for costs associated with handling and distributing the donated products, and for complying with any tracking or reporting requirements. Consider whether funding or technical assistance to manage the donation can be secured from other partners or sources.
- If donors are unreliable or have erratic delivery dates, suggest they donate nonessential items.
- Specify important requirements such as minimum acceptable shelf life on delivery, language of instructions and labels, and delivery dates when supplies will be needed.

- Suggest donors find other ways to support the HIV counseling and testing program when donations of commodities will cause more harm than good.

Distribution

For HIV testing commodities, the principles of stock control, storage management, and delivery to service delivery points are the same as for other medicines and supplies. However, the characteristics of rapid HIV test kits present some specific challenges for distribution—

- Short shelf lives require that stock held at various stages of the procurement and distribution cycle (pipeline stock) be kept to a minimum. The number of levels where stock is held in a supply chain (for example, in central, regional, and district stores) and the quantity of buffer or safety stock held at each level affect the amount of stock held in the pipeline.
- Some products require refrigeration during storage and transport. In climates where storage temperatures routinely exceed 20–30°C, many HIV test kits will require cold storage until distributed to the point of use.
- Delivery schedules need to be synchronized to ensure that all the products and supplies needed to perform testing are available at the point of service.
- Because scale-up of HIV counseling and testing services may go faster or slower than anticipated, points of service may need to requisition supplies from central stores more frequently, place nonroutine orders, and return excess stock or stock close to expiry to avoid stock-outs or wastage.

Steps in Distribution
1. Port clearing
2. Receiving and inspecting the shipment
3. Stock control
4. Storage management
5. Requisitioning supplies and delivery to health facilities
6. Reporting of consumption

A distribution plan that details numbers and locations of points of service served, quantities needed, and delivery schedules will help program and supply managers ensure that the available HIV testing commodities are delivered where they are needed, when they are needed. The plan should be updated regularly to adjust distribution quantities and schedules where scale-up of HIV counseling and testing programs proceeds faster or slower than expected. Good inventory management practices, including accurate record keeping at the point-of-service level and a management information system that is able to collect, analyze, and report information to the team responsible for developing the distribution plan at the central level, are keys to success. Management information systems are discussed in more detail in the chapter “Issues to Consider for Commodity Management for HIV Counseling and Testing Programs.”

As countries plan for universal access to HIV counseling and testing, the level of scale-up required in many countries will challenge even those HIV testing commodity supply systems that are currently working well. Some of the issues encountered by programs are described in the following box. Investing in building the capacity of distribution systems for going to scale is

discussed in the chapter “Issues to Consider for Commodity Management for HIV Counseling and Testing Programs” under Financing.

Country Experiences: Storage and Distribution Issues Encountered for HIV Test Kits

- In many countries, the lengthy procedures for clearing goods at the ports of entry contribute to shipment delays and further reduce the already short shelf life of these products.
- Higher-than-recommended storeroom temperatures caused inaccurate results in some geographical regions in one country. Air-conditioning the storage areas resolved this problem.
- Remote or small rural centers do not have refrigeration, and existing refrigerators at district hospitals and facilities “have no space” for HIV test kits.
- Stores staff split boxes of HIV test kits inappropriately and issue tests without enclosed accessories or controls when kits are in short supply.
- With no distribution plan in place, the central store distributes HIV test kits on a “first-come, first-served” basis. The lack of procedures for reordering leads to overordering by some sites, so stock quickly runs out at the central store and orders arriving later go unfilled. As a result, some district stores and service delivery points are oversupplied and others undersupplied.
- The distribution system is “more friendly to stores than to users.” Excess or short-dated stock is difficult to return for redistribution. Sites have to use their own transport to collect orders from central or district stores, which is not always available.

Source: MSH/RPM Plus.

In addition to working with partners to rationalize multiple vertical supply systems, another major challenge that many program and supply managers face is organizing the distribution system to keep pipeline stock to a minimum while also delivering supplies at frequent, usually monthly, intervals to an ever-increasing number of service delivery points. Because of the short shelf life of many rapid HIV test kits, keeping the products at one central location and distributing them directly to the service delivery point at frequent intervals would be the preferred model. Indeed, for many countries, this distribution model was used when starting up their VCT programs. However, distribution from one central point directly to points of service is generally not viable in geographically large countries, and the capacity of such a system can be quickly exceeded in others as the number of sites providing HIV counseling and testing increases. As managers explore options for reorganizing and rationalizing existing distribution systems for HIV testing commodities in preparation for going to scale, some programs have centralized storage at the national medical stores and use a relay system to move supplies to regional and district levels. A central management unit responsible for coordinating distribution and communicating with point-of-service staff, and a robust information system to feed data on consumption or requirements to the central unit, are required for this type of system to work well. (See Zambia case study in the chapter “Commodity Management for Taking HIV Counseling and Testing Programs to Scale.”)

Other programs, especially in geographically large countries, have decentralized storage of rapid HIV test kits to one or more levels in the health care system. As mentioned earlier, limiting the number of levels where stock is held in a system to central and district levels, for example, and omitting regional stores as well as reducing safety or buffer stocks can decrease the amount of

stock held in the pipeline and hence wastage. A mechanism to supply nonroutine orders from the central to the decentralized store is essential for avoiding stock-outs when safety stock is decreased. Budgeting for renovations to ensure adequate storage space is available at appropriate temperatures before decentralizing storage is another key consideration because rapid HIV test kits can be bulky and the existing capacity in vaccine and essential medicines storage areas is quickly exhausted. Finally, some programs pay for international or local suppliers to deliver supplies directly to districts or even the point-of-service level. However, the fees charged can be considerable and should be carefully negotiated as part of the procurement package.

Storage and Stock Control of HIV Testing Commodities

Good storage and inventory control practices at the national and the point-of-service levels are similar. Written SOPs that document accepted practices for ordering/requisitioning, receiving, inventory management, and issuing and disposing of expired stock should be available at all levels.

Important questions for storing HIV testing commodities include—

- Do any of the commodities have special storage requirements? Is adequate refrigerated or cold storage space available? Is the electricity supply reliable, or is a reliable backup generator available to run refrigerators and equipment?
- How much room is needed to store all the commodities between deliveries? Can more storage space be found or more frequent deliveries be scheduled? If scaling up is planned, where will additional commodities be stored?
- Are HIV testing commodities adequately protected from sunlight and moisture? Are products stored off the floor?
- Is the storage area secure to prevent pilferage and to protect clients and their children from accidental harm from HIV testing commodities, specimen collection equipment, or medicines? Is access to the storage area restricted to authorized staff only?
- Is a procedure in place for a “cold chain” to maintain and monitor special storage temperatures from delivery of the commodity to storage and use? Are supplies to transport heat-sensitive commodities, including cool boxes and icepacks, adequate? What system is in place to regularly monitor refrigerator and storeroom temperatures?

Important principles of stock control include—

- **Stock rotation**
 - Because rapid HIV test kits have short shelf lives, issuing and using the stock with the shortest expiration date first is essential. Boxes should be clearly marked with expiry date, and stock should be organized with the shortest shelf life to the front.

- An example of a form for tracking the expiry dates of HIV test kits to alert supply managers when stock should be removed from stock for exchange or destruction is included in Annex B.
- **Record keeping**
 - At the national or point-of-service level, it is essential to have a system to track commodities to determine how much and when to order.
 - The system does not necessarily have to be computerized; an accurate, up-to-date manual system is an important first step for computerizing a system.
 - The stock control records or computerized system should be able to distinguish between what is used and what is wasted and to monitor losses for auditing purposes. An example of a stock card is shown in Figure 2; instructions on how to use the stock card are included in Table 2.
 - Use a different card for each product and pack size, and record the date every time a supply is received or issued, or when expired stock is removed for destruction.
 - Keep a running total of the quantity left, and check the stock regularly (for example, once a month); make a record of any discrepancies on the card.
 - The minimum stock level, reorder level, quantity, and delivery time can also be recorded on the card if these factors are used for procurement.
 - Records should be regularly audited by a supervisor or person external to the stores staff to check adherence to good record-keeping practices and to monitor losses.
- **Requisitioning and issuing stock**
 - At service delivery points where HIV testing is increasing, commodities should be requisitioned on a regular and frequent basis, usually once a month, especially where rapid HIV test kits have short shelf lives.
 - If usage is continually increasing, recalculate the minimum stock level, the reorder level, and the reorder quantity every time an order or requisition is prepared.
 - Ensure that staff responsible for requisitioning HIV testing commodities have the necessary skills and tools to quantify needs accurately.
 - Inform stores staff of the importance of issuing complete boxes of rapid HIV test kits, where appropriate. Mark stock cards and shelves accordingly.
 - As a general principle, stock with the shortest expiry date should be issued first. Inform stores staff and document exceptions, for example, when issuing stock to remote sites or to points of service that test small numbers that will be burdened with unusable stock.

- **Expired stock**

- A system should be in place to ensure that expired stock is removed and destroyed safely.
- It is important to have a national and point-of-service-level policy to provide guidance on the safe disposal of expired stock and other biohazardous waste.

Product Name: Determine HIV-1/2							Card No: /							
Strength:		Dosage Form: 1 test		Issue Unit: 100 tests		NSN: 1800978								
Size:		RECORD OF ORDERS, RECEIPTS & ISSUES					Est. Reorder Level: 1000 tests							
Date	Requisition No.	Quantity Ordered	Voucher No.	To/From	Quantity Received	Quantity Issued	Stock Balance	Unit Price	Remarks					
19/10/08							1,000		Stock check /JP Lot 036 EXP 10/08 (200) Lot 047 EXP 1/09 (800)					
10/11/08	88009	2,000		CMS			1,000		KP					
10/11/08				VCT clinic		200	800		JP					
11/11/08				Hosp		300	500		Kw. Borrowed					
20/11/08			88009	CMS	2,000		2,500	14.50/100	Lot 052 EXP 9/10 JL					
21/11/08				Expired		200	2,300		Lot 036 EXP 8/08 JL					
22/11/08							2,100		Stock check/ JL Lot 047 EXP 1/09 (100) Lot 052 EXP 9/10 (2000)					
TOTAL MONTHLY ISSUES														
Fiscal Year	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Usage	Expired
FY: 08/09							1800							
FY: /														
FY: /														

Figure 2. Sample stock card

Table 2. How to Use the Stock Card

Column	Information Entered
1. Entering the Opening Balance	
Date	Enter the date stock is checked (e.g., day/month/year)
Stock Balance	Enter the usable (unexpired) quantity in stock (e.g., 1,000 tests)
Remarks	Enter the words "stock check" and the initials of the person who checked the balance Enter the lot number, expiry date and for multiple lots, quantity, of each lot in stock
2. Ordering Stock	
Date	Enter the date stock is ordered (e.g., day/month/year)
Requisition No.	Enter the assigned requisition or order number
Quantity Ordered	Enter the quantity ordered (e.g., 2,000 tests)
To/From	Enter the place or institution from which the goods have been ordered
Stock Balance	Stock balance will equal previous balance
Remarks	Enter the initials of the person who placed the order
3. Tracking Loans	
Date	Enter the date stock is borrowed (e.g., day/month/year)
To/From	Enter the location the goods are loaned to or borrowed from
Quantity Received or Quantity Issued	Enter the quantity issued or received (e.g., 300 tests issued)
Stock Balance	Stock balance will equal previous balance minus the quantity loaned or plus the quantity borrowed
Remarks	Enter "Borrowed from" or "Loaned to" and the initials of the person who issued or received the goods and lot number and expiry date when stock is received
4. Receiving Stock	
Date	Enter the date stock is received (e.g., day/month/year)
Voucher No.	Enter the order number
To/From	Enter the supplier's name
Quantity Received	Enter the quantity received (e.g., 2,000 tests)
Unit Price	Enter the price per unit (e.g., 14.50 per 100 tests)
Stock Balance	Stock balance will equal previous balance plus the quantity received
Remarks	Enter the lot number and expiry date of the stock received Enter the initials of the person who received the goods
5. Issuing Stock	
Date	Enter the date stock is issued (e.g., day/month/year)
To/From	Enter the place or provider the goods are issued to
Quantity Issued	Enter the quantity issued (e.g., 200 tests)
Stock Balance	Stock balance will equal previous balance minus the quantity issued
Remarks	Enter the initials of the person who issued the goods
6. Stock Check	
Date	Enter the date of the stock check (e.g., day/month/year)
Stock Balance	Enter the physical count of stock held
Remarks	Enter "Stock Check" and the initials of the person who checked the balance Enter the lot number, expiry date and for multiple lots, quantity, of each lot in stock

Delivering and Collecting HIV Testing Commodities and Specimens

Distribution presents unique challenges to planners and decision makers at the national level when improving geographical access to HIV counseling and testing is a goal. Programs are working to make distribution systems more flexible and responsive to users by increasing the frequency of deliveries, collecting and redistributing excess or short-dated stock, and processing nonroutine orders. The move to expand the range of service delivery models and go beyond the public sector requires new approaches for getting supplies to initiatives such as mobile units and door-to-door programs and to programs operating at health facilities and stand-alone sites in the NGO and private for-profit sectors. Moreover, as countries move to improve access to PCR testing for infants and children, the quality and reliability of the service will depend on the effectiveness of the transportation system in getting specimens to the central or regional laboratory for testing. The cost of transporting HIV testing commodities to remote areas or transporting specimens back to laboratories for testing can be considerable.

Options to improve the distribution system include—

- Strengthen and integrate into or use the existing distribution system.
- Use autonomous private or parastatal companies. Autonomous supply agencies are often constituted as parastatals, under either the ministry of health or an independent organization with a board of directors from several government ministries. They operate as nonprofit supply services, and their primary clients are government health services.
- Set up a parallel distribution system.
- Use a combination of mechanisms. For example, use existing public sector transport for routine orders, and lease private vehicles or use courier/express mail for emergency orders.

When planning transportation system improvements, it is essential to thoroughly review the existing system to ensure efficient and rational use of existing resources. Current operating costs should be accurately assessed and compared with the projected cost of alternative systems. Options for strengthening existing distribution systems may include strengthening supervision of staff and rationalizing routes and schedules. Another strategy to improve the existing distribution system is to review the transportation terms for overseas and in-country suppliers and investigate the possibility of requiring direct delivery to lower-level stores.

Using private or parastatal companies can provide cost-effective alternatives for storage and distribution, especially at national or regional level. Although contracting out distribution to the private sector can create more work—such as assessing the cost of existing systems, preparing tender documents, specifying service requirements, assessing the tenders, and monitoring contractor performance—it also has the potential to improve efficiency. In some cases where services are to be provided on an “as needed” basis, a memorandum of understanding with a contractor may suffice, thereby avoiding a lengthy contracting process.

Ethiopia: Approaches to Meeting the Challenges of Distributing Rapid HIV Test Kits

Ethiopia's geographical size, the lack of all-weather roads to some facilities, ambient temperatures in some regions that frequently exceed 30°C, and the need to serve an increasing number of testing sites are some of the challenges faced by the supply management team. Several strategies used to address these challenges are described below.

- Rapid HIV test kits are held at storage facilities at all levels—central, regional, and district—to facilitate distribution. However, buffer stocks are kept to a minimum at each level to avoid wastage and because the infrastructure at many district pharmacies is insufficient to store large quantities of these products.
- The HIV/AIDS Prevention and Control Office (HAPCO) of the MOH, the Pharmaceutical Fund and Supply Agency, the Ethiopian Health and Nutrition Research Institute, and PEPFAR-funded SCMS will jointly manage the quantification, procurement, and distribution of rapid HIV test kits to ensure that efforts are well coordinated.
- MoH/HAPCO has initiated regular three-monthly campaigns to increase awareness and uptake of HIV testing.
- Quantification of needs and distribution planning are synchronized with plans for scale-up campaigns to enable sufficient quantities to be purchased and distributed.
- Staff deployed to the regions by MSH/RPM Plus and SCMS to support MoH/HAPCO in the distribution of kits to health facilities assist with responding to nonroutine orders as part of their duties. A combination of transport mechanisms, including air, land, and courier services, is used, according to the geographical context.
- Staff awareness on the proper storage of rapid HIV test kits at the point-of-service level has been raised through trainings, by mentoring, and by introducing temperature monitoring charts. The needs for cold and refrigerated storage space are addressed on a case-by-case basis.
- RPM Plus assists the government to request Determine™ HIV-1/2 test kits through the Axios Foundation for the PMTCT donation program, and to distribute, monitor, and report on usage of the test kits.

Source: MSH/RPM Plus Ethiopia office.

The temptation for donors to set up parallel distribution systems can be considerable. However, although vertical distribution systems may solve a specific problem at a specific time, they are costly to set up. In addition, systems heavily subsidized by donors are not generally financially sustainable after donors discontinue funding. Before setting up additional parallel systems, donors and donor-funded technical assistance groups should ensure that all existing transportation options are thoroughly reviewed to assess whether using (and strengthening) an existing system would be more sustainable over the long term.

Key considerations include—

- Rationalizing supply systems to keep transportation and administrative costs down
- Using existing distribution systems and schedules where possible, and coordinating the collection of commodities from different sources
- Sharing vehicles among programs to reduce costs and improve reliability

- Maintaining the cold chain during transportation for commodities and specimens that need continual refrigerated storage
- At the point-of-service level, keeping the number of separate suppliers used to a minimum

More information on distribution of HIV test kits and other HIV/AIDS-related commodities is available in the “Additional Resources” chapter.

Use of HIV Testing Commodities

Access to rapid HIV test kits and other commodities alone does not ensure an HIV counseling and testing program of acceptable quality. Specimens must be correctly labeled and the information correctly recorded to ensure that clients are given correct results. National HIV testing algorithms need to be available and to be followed at the point-of-service level to guide the selection and order of use of rapid HIV tests. Instructions for using HIV test kits must be followed correctly, and staff may need specialized training in reading results. Necessary support services, such as reference laboratories and supervision, may need to be developed or strengthened to monitor and evaluate the testing performed in some settings. Information leaflets must be available and given out appropriately. Finally, clients and providers need to have confidence in the accuracy and reliability of HIV testing services to accept and act on the result.

Some interventions offered as part of HIV counseling and testing services may require medicines or other commodities, for example, co-trimoxazole preventive therapy. Not only must medicines be correctly prescribed and dispensed, but clients also must take the medicines correctly. Unbiased drug information that staff can understand must be available to enable informed decisions. Tablet containers and medicine bottles will be needed for dispensing medicines, and instructions for clients must be clear and legible. Standard treatment guidelines, together with a national essential medicines list, can help standardize and rationalize prescriptions and can be used for in-service training, supervision, and medical audits.

Key considerations at the national level include—

- Have standard testing algorithms and relevant standard treatment guidelines been distributed to HIV counseling and testing service delivery points in both the public and private sectors?
- Have SOPs for performing HIV testing and for collecting, storing, and transporting specimens been developed, tested, and disseminated to service delivery points? Do training materials need updating, and are job aids available to assist staff to perform testing correctly?
- Has a minimum set of standards been defined that a point of service is required to meet? Is distribution of HIV testing commodities restricted to service delivery points that have met these standards?

Questions to ask at the point-of-service level include—

- Are standard testing algorithms and relevant treatment guidelines available and accessible to every staff member who needs them? Do staff have a written, updated protocol to follow?
- Are staff trained to handle specimens and HIV test kits safely and appropriately? Do they need training updates for new tests or procedures? Are a written SOP and a job aid available for performing each test?
- Do staff have the equipment (for example, timers) that they need to follow HIV testing instructions accurately? Where results are read visually, is lighting adequate to correctly interpret the result?
- If HIV counseling and testing services include services that require medicines, is information available on using the medicines safely and effectively? Does the information detail side effects, which medicines cannot be given together, and when the medicines should not be used? For example, how will staff know which medicines cannot be given to pregnant women?
- Are staff trained and experienced in diagnosing and prescribing appropriate medicines to ensure that the right medicine is given in the right dose for the right length of time? Is a system in place for dispensing and labeling medicines to ensure that the right medicines are dispensed, labeled correctly, and given to the right person?
- Does a system exist for follow-up on the acceptability of products and services to customers? Do clients and providers have confidence in the accuracy and reliability of HIV testing services? Are clients able to adhere to the medicines treatment schedule?

ISSUES TO CONSIDER FOR COMMODITY MANAGEMENT FOR HIV COUNSELING AND TESTING PROGRAMS

Policy and Legal Framework

It is important to be familiar with the policies and legislation that are relevant to managing commodities for the HIV counseling and testing program, including—

- The national HIV testing policy and the national laboratory policy, specifically recommendations for—
 - Evaluating HIV test kits and developing national algorithms for VCT and other HIV testing contexts within the country
 - Scaling up to universal access, including expanding PITC and access to testing for infants and children
 - Using rapid testing as an alternative to ELISAs, serial or parallel testing, and managing discordant results
 - Point-of-service requirements for performing HIV testing, such as minimum standards or formal systems for accreditation and certification
 - Personnel permitted to perform tests and requirements for training and certification
 - Record keeping and information management
 - Quality assurance, including procedures for running internal and external quality controls
 - Health and safety procedures, including supplies needed for universal precautions
- The national medicines policy and pharmaceutical legislation and regulation, specifically requirements for—
 - Product registration including procedures for obtaining fast-track approval
 - Regulating the importation, quality assurance, distribution, prescribing, dispensing, or use of medicines and commodities
 - Legal aspects of commodity procurement including legislation and agreements on patent protection
 - User fees, including exemption and waiver policies for HIV testing and treatment services
- Donor-specific policies and regulations for funding procurement of health commodities

Regulatory agencies in resource-constrained countries often lack the capacity to conduct dossier evaluation of diagnostics, and many countries recognize efficacy and safety evaluations by another medicines regulatory authority, particularly countries participating in the International Conference on Harmonization, as “proxy evaluations.” Because existing DNA and RNA PCR technologies do not have licensing approval for use in routine diagnostic services in the United States or Europe at the time of writing this document, planners and program managers may need to seek technical assistance from specialized agencies to meet regulatory requirements for these products before they can be purchased.

Policy decisions made at the point-of-service level should include decisions on whether to use ELISAs or rapid tests, whether to perform serial or parallel HIV testing, and what procedures to use for resolving discordant results. Decisions will also need to be made on which services to provide as part of the HIV counseling and testing package and procedures for referring clients for others, on using “opt-in” or “opt-out” approaches for PITC, and on charging user fees for HIV testing services and for issuing exemptions and waivers if relevant. Program managers should ensure that they can comply with legislation that controls the manufacture, supply, storage, prescription, and dispensing of medicines when interventions that require medicines will be offered as part of the package.

The existence of policies and guidelines alone does not mean that recommendations will necessarily be adopted or adhered to. Experiences in developing and implementing policy changes have shown that engaging stakeholders in the policy development process and obtaining the endorsement of stakeholder groups for national guidelines are key strategies for success. In particular, it is important to involve professional associations early in the process to facilitate adoption of the new policy by private practitioners. The dissemination of new or revised guidelines and policies to program managers and frontline workers needs to be accompanied by sensitization and training of the health care workers in both the public and private sectors and also of the community partners providing services, where relevant. Similarly, at the point-of-service level, staff are more likely to adopt local policies and adhere to SOPs for supply management and performing HIV testing if they have been partners in developing them. Resources need to be made available to allow supervisors to monitor adherence to policies and guidelines on a regular basis and to work with staff to clarify misunderstandings and resolve constraints to following recommendations.

Financing

For many resource-constrained countries, achieving the exponential increases in HIV counseling and testing capacity needed year after year to meet the target dates for universal or 80 percent access will depend on their success in securing external sources of funding. The process for developing realistic plans for scaling up services, costing requirements, writing proposals, gathering information to support the request, and eventually disbursing funds can be lengthy and unpredictable depending on the donor. Success in attaining future funding will usually require country and HIV testing site managers to account for expenditures, including those for HIV testing commodities, and demonstrate results. Ensuring that scale-up is not constantly stalled by funding constraints in the long term will depend on building the capacity of planners and

program managers not only to plan, cost, and secure funding but also to lead and manage the process.

When developing a national or point-of-service-level budget for scaling up HIV counseling and testing services, it is important to think about all the potential costs associated with procuring and managing supplies. In addition to financial requirements for procuring HIV test kits and other commodities, consider

Developing an **HIV testing commodity financing strategy** as part of an overall strategic plan for scaling up is a high priority at both the national and facility levels. The financing strategy should include efforts to **improve the use of existing funds** by enhancing efficiency in the commodity management system. The one-to-two-year forecasts of commodity needs and requirements for building the capacity to manage (select, procure, distribute, and use) products should be used to prepare a budget and assist planners and program managers to **identify the shortfall and mobilize resources to fill the gap**. The VEN analysis can be used to prioritize expenditures if delays in disbursement of funds occur.

other recurrent expenditures, such as procurement fees or markups, and costs associated with shipping, importing, storing, and delivering the products. Before accepting donations, it is important to establish who will be responsible for covering these costs, which can be substantial, especially if the country or program is obliged to set up a vertical distribution or special reporting system to meet donor requirements. Other periodic expenditures to consider include printing inventory management forms; updating, printing, and disseminating testing algorithms or guidelines; training staff, for example, in good inventory management practices; maintenance contracts for equipment; and disposal of expired stock and waste. You may want to include some contingency fees for unplanned activities, for example, to cover emergency procurements. Human resources costs may include assigning a part- or full-time individual to coordinate procurement and distribution of supplies at the national level, and allocating staff time to collect, analyze, and report data at point-of-service level.

Financial resources may need to be invested to build the capacity of the commodity management system to support program scale-up at both the point-of-service and the national levels. Consider costs for acquiring refrigerators, establishing temperature-controlled storage areas, improving the security and integrity of storage sites, leasing or purchasing vehicles, obtaining cool boxes and icepacks for maintaining the cold chain during transport, and building incinerators for disposal of waste. Resources will usually be needed to develop and maintain a management information system to track commodities and monitor usage, regardless of whether manual or computerized methods are used. Costs for technical assistance needs, for example, for external assistance to prepare forecasts of commodity needs, should also be incorporated into the budget. Integrating the supply management of rapid HIV test kits and other testing commodities into existing systems for essential medicines and laboratory supplies can allow these capacity-building costs to be shared across programs and ultimately improve supply management for a wider range of products. Donors may be more willing to invest in system strengthening if they know that activities will be cofunded from other sources; however, planners will need to develop an overarching multiyear plan for strengthening the commodity management system and to establish mechanisms for coordinating inputs. See the “Additional Resources” chapter for further information on determining resource needs and creating budgets.

After the budget has been developed, the next step is to map out existing or committed future sources and levels of funding, identify the shortfall, and mobilize resources to fill the gap. Funding needs and options to increase funding will vary with countries and context. Financial sustainability of HIV counseling and testing programs is likely to require a combination of financing mechanisms to meet expanding needs.

Options for increasing funding include the following—

- Present justification for greater government funding.
- Obtain or increase donor assistance.
- Increase or add health insurance coverage for HIV testing.
- Encourage the private sector to offer HIV counseling and testing as part of workplace medical schemes or benefits.
- Introduce or increase user fees (cost sharing).

Funding for commodity procurement and supply chain management for an HIV counseling and testing program may come from multiple sources, including bilateral and multilateral donors, the Global Fund, and private foundations. Because donors often have different proposal cycles and requirements as well as differing areas of interest or expertise, identifying mechanisms to coordinate proposal development and donor inputs is important. The team responsible for developing the procurement and distribution plan will need to work with donors to align procurements with disbursements and to identify emergency funding from an alternative source if disbursements are unexpectedly delayed. The coordinating team should also be familiar with donor-specific policies and requirements related to procurement of medicines and commodities. USAID maintains a list of rapid HIV test kits that are approved for procurement using USAID funding on its website.²⁸ The procurement and supply management policies of the Global Fund are discussed in the following box.

Donors will want to evaluate the results of the funding given, so having a functioning management information system to collect data that can be used to evaluate the program is important. When large amounts of medicines and commodities are being procured and distributed, corruption and pilferage can become a problem. Donors will require good bookkeeping and accounting systems to ensure that resources are managed efficiently. Separating key responsibilities, ensuring proper cash management, providing regular auditing of financial procedures, and making audit reports public all help improve accountability and transparency.

²⁸ http://www.usaid.gov/our_work/global_health/aids/TechAreas/scms/scms.html.

Global Fund Policies on Procurement and Supply Management

The main objective of Global Fund procurement policies is to procure quality-assured products at the lowest prices in accordance with national and international laws. Procurement must be conducted in a transparent fashion. The objective of the Procurement and Supply Management (PSM) plan is to outline how the Principal Recipient will adhere to Global Fund procurement policies. It is also used to measure performance during implementation.

Once a proposal submitted to the Global Fund is approved, the Principal Recipient is required to submit a PSM plan. The Local Fund Agent then conducts a PSM assessment, and if the plan is considered adequate and the proposal is approved, the Global Fund may start disbursement of funds for procurement. Alternatively, the Global Fund may request that the PSM plan be revised if it is determined to be inadequate. The PSM plan covers two implementation years; any significant changes in that time must be approved by the Global Fund. The Global Fund's policies on procurement and supply management and the template for developing a PSM plan are laid out on its website at www.theglobalfund.org.

Several countries have reported delays in disbursement of Global Fund grants caused by difficulties in developing PSM plans or getting them approved. It is important to begin developing PSM plans in good time because experience shows that difficulties are most often encountered in collecting and verifying data to support the plan, forecasting needs, and developing and budgeting strategies to strengthen commodity management systems. Having a national coordination subcommittee or working group in place to coordinate procurement and supply management, including quantification and capacity building, can facilitate some of these processes. Countries may also need to incorporate requirements for technical assistance to support implementation into their budget and plans, for example, for ongoing quantification.

User fees for HIV testing must be locally appropriate, and exemption systems must be established to ensure that user fees do not act as a deterrent to testing, particularly for services targeted to special populations such as the poor, youth, and other vulnerable groups. In a recent study in Tanzania, offering HIV tests for free was shown to be more cost-effective in preventing HIV infections than charging a fee, because three times as many people came for testing when user fees were eliminated.²⁹ In addition, experience with revolving medicine funds and broad user-fee programs has shown that programs designed with little attention to management and accounting systems have experienced substantial abuse and little revenue relative to the cost of fee collection.

Management Information Systems

A commodity management information system collects, analyzes, reports, and facilitates interpretation and use of information at both the point of service and higher levels for decision making. All four primary components of the commodity management cycle, and especially procurement and distribution, depend on the timely reporting of accurate information to function effectively. The recent difficulties experienced by programs in resource-constrained settings in collecting data to forecast needs for a Global Fund PSM plan or to justify renewal applications

²⁹ N. M. Thielman, et al. 2006. "Cost-Effectiveness of Free HIV Voluntary Counseling and Testing through a Community-Based AIDS service Organization in Northern Tanzania." *American Journal of Public Health* 96 (1): 114–19.

for HIV test kit donations for PMTCT are indicative of the weakness of existing commodity management information systems. As countries develop plans and budgets for taking their HIV counseling and testing programs to scale, the errors introduced by weak information systems in the management of commodities will become magnified. Thus, it is critical to incorporate strategies for building and maintaining an effective commodity management information system to ensure the adequate availability of HIV testing commodities to prevent interruption of services.

Importance of a Functioning Commodity Management Information System

Accurate and timely information is essential to help program and supply managers to—

- Quantify how much and when to order
- Calculate funding needs and storage requirements
- Plan procurement and distribution quantities and schedules to minimize expenditures on emergency procurements and deliveries
- Monitor appropriate use, review actual consumption of HIV testing commodities and rate of scale-up of services, and adjust procurement and distribution quantities accordingly
- Keep track of expiring commodities so that necessary measures to minimize wastage can be taken, for example, returning short-dated stock so that it can be used by a higher-volume testing site
- Improve accountability and maintain an audit trail to track commodities that enter or leave the supply system, especially to monitor losses
- Account for expenditures on commodities to governments and donors and demonstrate results to support proposals or justify requests for ongoing funding
- Monitor the performance of the commodity management system as operations expand to identify problems early and address them promptly

As national governments work with their partners to rationalize multiple vertical supply systems, an important step is to standardize data collection tools and reporting systems and structures. Information systems for donor-funded vertical programs are usually designed to meet the specific reporting requirements of the funding source. The challenge in rationalizing multiple parallel commodity management information systems lies in reaching agreement on a minimum set of data that the system will report on to avoid overloading it. Furthermore, success will depend on designing an information system that can track products and report usage and inventory data by funding source and program.

Before scaling up a commodity management information system for HIV counseling and testing programs, ensure that the system—

- Includes the optimal set of data elements selected through a participatory process that includes donors, stakeholders and users at both the central level and point-of-service level

- Uses simple procedures and formats for easy data collection, processing, analysis, and presentation
- Has tools and procedures to generate information for decision making and facilitates the use and sharing of information
- Includes procedures to crosscheck entries and validate data
- Is well documented with a procedure manual
- Facilitates analysis of data by geographic levels, funding source, type of testing site, and program
- Uses carefully selected indicators, with clearly defined numerators and denominators, to monitor performance
- Incorporates a feedback system
- Is computerized at appropriate levels and after successful implementation of a manual system

Examples of a commodities report form designed for use at a stand-alone VCT center and a laboratory test reporting form designed for use at a site with multiple service delivery points are attached as Annex C. See “Additional Resources” chapter for more information on recording and reporting formats.

An HIV testing commodity management information system should report the following minimum data elements at point-of-service level—

- **Quantity of product used:** usage for testing and for quality control, reported by funding source and service type. Ideally, actual usage rather than issues data (quantity issued by the storeroom to the point of use for example, the laboratory) should be reported where possible, especially for low-use items such as tiebreaker tests.
- **Quantity in stock:** usable stock (not expired or damaged) on hand, reported by funding source and program.
- **Short-dated stock:** stock that has high chances of expiring before it can be used.
- **Losses:** stock that is damaged, wasted, or expired, or stock that cannot be accounted for.

Source: Adapted from DELIVER. 2006. *Building Blocks for Inventory Management of HIV Tests and ARV Drugs: Inventory Control Systems, Logistics Management Information Systems, and Storage and Distribution.* Arlington, VA: DELIVER for the U.S. Agency for International Development.

Zambia: A Case Study on Strengthening the Commodity Management Information System for Going to Scale

In 2002, Zambia Voluntary Counseling and Testing Services (ZVCTS) identified the need to streamline information services and specifically to strengthen the commodity management information system at point-of-service and national levels as part of national efforts to scale up VCT services. USAID funded MSH/RPM Plus to provide technical assistance to ZVCTS to develop a comprehensive management information system that would collect VCT-related information from the countrywide network of VCT sites, aggregate it, automate where possible, and analyze it for use in planning, supervision, and monitoring of program activities.

A rapid assessment conducted to better understand the management functions, information needs, and current practices of the existing information system revealed that—

- A uniform VCT management information system did not exist, making comparison across VCT sites difficult. Several different systems were in use, and the system in place depended on the NGO running or the donor supporting the site. VCT data were not included in the national Health Management Information System.
- Records, registers, and forms were often in short supply at VCT sites.
- Commodity management tools to collect, analyze, and report data were generally absent, and the resulting inaccurate estimates of the HIV test kit requirements led to wasted supplies, stock-outs, and higher costs to the government for emergency orders.
- Staff were not adequately trained on the tools and systems in place, and several supervisors reported that staff were not filling in the VCT registers correctly. Written procedures for the collection, analysis, and reporting of VCT-related information did not exist.
- No automated systems were in place, and apart from a few exceptions, capacity for an automated system was limited to the district level and above.
- Data were collected with the sole purpose of reporting to the ZVCTS and were not used for programmatic purposes at the testing site. Staff lacked ownership of the existing systems.
- Some sites did not have a mechanism to report to the national office, resulting in underreporting. There was no evidence of information being used at the central level for making decisions.
- Indicators were not used to monitor the performance and effectiveness of services.

Based on these findings, ZVCTS decided to standardize the various tools and reporting systems in place, redesign the existing VCT information system to make it more user-friendly, and train health care workers to use the information generated for decision making at all levels. In order to build ownership of the new system, a participatory process was used to redesign the new information system. In 2002, all stakeholders involved in VCT service provision, including donors, UN agencies, NGOs, and point-of-service-level staff were invited to a consensus workshop coordinated by ZVCTS to agree on a well-defined set of indicators and an optimal number of data elements that would be used to develop a standardized information system for all VCT sites, regardless of ownership or funding.

(Box continues on next page)

Zambia: A Case Study on Strengthening the Commodity Management Information System for Going to Scale, continued

The new information system was piloted in four districts and then rolled out countrywide. A procedure manual was developed, tested, and disseminated to all sites. Training was conducted at the point-of-service, district, province, and national levels and followed up with support by supervisors to check on how users were coping with the new system. The system was rolled out manually and gradually automated. It is maintained at the district level—the district officer is responsible for aggregating data and generating and forwarding reports to ZVCTS. In 2003, ZVCTS, encouraged by the success of the redesigned system, expanded the management information system to incorporate PMTCT services, with the cooperation of the PMTCT stakeholders.

Positive features of the system, as reported by users, include—

- The simple “tick” registers with prefilled columns have improved data capture on service provision and accounting of HIV testing commodities.
- The data elements needed to complete the monthly returns can be prepared from one register.
- The structured feedback mechanism has improved motivation of service providers in collecting and submitting data. The computerized database managed at the district has improved the timeliness and quality of feedback reports to service delivery points.
- The commodity management data collection tools provide more reliable data that can be used to project commodity needs.
- User-friendly manuals are available for quick reference in case providers “get stuck.”

However, improvements are still needed. The printing of registers and forms is still problematic; regular data audits are needed to verify data accuracy; and indicators and recording and reporting tools need to be reviewed in light of evolving program demands and new service delivery models. Also, ongoing training is needed as new staff come on board, along with refresher training to encourage and enable staff to sustain operations and overcome challenges as programs scale up.

Source: MSH/RPM Plus.

Human Resources

The importance of ensuring that national and local HIV counseling and testing programs are adequately staffed—meaning that staff have the required technical and management capacity and are adequately and regularly compensated—cannot be overemphasized. At stand-alone VCT sites, commodity management requires that staff have skills and knowledge not only in clinical and technical areas (e.g., specimen collection, performing HIV testing, and counseling clients) but also in supply issues such as quantification and inventory control. At the point-of-service level, it is important to identify who will be responsible for requisitioning and managing HIV testing commodities and to ensure that their job description reflects these additional responsibilities. Experience shows that poor inventory management practices are more likely to occur in points of service where responsibilities are not clearly delineated. Integrating supply management for HIV testing commodities into existing supply systems for other programs, for example, essential medicines, will avoid the need to train clinic staff in commodity management

and also allow staff at the HIV counseling and testing clinic to focus on their core responsibilities.

Monitoring and evaluating staff skill levels are critical, particularly as the program expands to incorporate new interventions. Some activities can be extremely complex, and decentralizing all commodity management functions, such as procurement and quality assurance, to the point-of-service level may not always be feasible or desirable. As programs scale up, assigning a part- or full-time individual at the national level to coordinate procurement and distribution of supplies may be necessary.

It is important to determine the skills and knowledge required for commodity management within the HIV counseling and testing program and to take an inventory of and prioritize staffing and training needs. In addition, stores staff may need to be sensitized to the special handling needs of rapid HIV test kits and other laboratory supplies and to the consequences of inappropriate storage. All too often, laboratory supplies are relegated to overheated corners of storerooms and issued without controls or essential accessories and well beyond their expiration date because “they are only test kits.” When defining staff requirements, ensure that staff have adequate time to perform critical tasks such as HIV testing and dispensing of medicines without interruption to minimize the potential for error. Program planners and managers can then use these requirements to plan for recruitment or training and also to approach the national coordinating body or donors for assistance in addressing these needs.

Monitoring and Evaluation

Monitoring and evaluation are an integral component of internal and external quality assurance procedures for all points of service where HIV testing is performed. (More information is available in the “Additional Resources” chapter.)

Certain indicators can be used to monitor the performance of the commodity management system for HIV counseling and testing programs to help managers identify problems and advocate for resources to address them. These indicators can be useful in evaluating the impact of an intervention designed specifically to address a commodity management problem and are essential for demonstrating results to donors.

As HIV counseling and testing programs scale up, monitoring a few indicators regularly can provide early warning of problems as the commodity management system expands operations and allow managers to take action to sustain quality services.

Existing mechanisms for monitoring and evaluation should be used where possible. The checklists used for self-monitoring by the laboratory or point-of-service supervisor and by the

Choose **5 or 10 products** (depending on the number of items in the inventory) for **the tracer list**. A sample list might include the screening and confirmatory HIV test kits, lancets, gloves, condoms, and information leaflets.

external quality assurance team for on-site assessments can be adapted to add selected commodity management parameters.

Alternatively, some HIV testing commodities can be included in the tracer medicine and commodity list used by supervisors to track the performance of the essential medicines and laboratory supply

systems. Experience from medicines programs has shown that it is not feasible or even necessary

to calculate performance indicators for every product handled by a supply system or even a stand-alone VCT site. For an HIV counseling and testing program, a list of 5 or 10 products that are important and widely used is usually sufficient.

The main commodity management indicator for monitoring and evaluation is—

- **Average percentage of time out of stock for a set of tracer commodities at an HIV testing site**
 - Time out of stock is the number of days a product was not present in the site storage area over a recent specific period, for example, the last six months. To be considered in stock, the product cannot be expired.
 - Ask for the inventory record or stock card for each tracer drug, and check the number of days the product has been out of stock over a recent specific period.
 - The average percentage time out of stock for a set of products at each site is calculated by summing up the percentage number of days during a specific period that each tracer commodity has been out of stock and dividing this figure by the number of products counted.
 - At national or program level, the indicator is calculated for a set of HIV testing sites by summing up the average percentage time out of stock for each site and dividing this figure by the number of sites counted.

Other suggested indicators for monitoring and evaluation include—

- **National HIV testing guidelines and/or algorithms exist and have been reviewed and if necessary updated in the past two years**
 - Ask the director of the national AIDS coordinating body or the National Reference Laboratory when the last review took place.
- **Percentage of HIV testing sites visited that have the most current edition of national HIV testing guidelines and/or algorithms available at all service delivery points**
 - Ask the facility or clinic manager to show the most recent copy of guidelines available at each service delivery point.
 - In a site with more than one HIV testing service delivery point, you must see a copy of the most recent guidelines at each service delivery point for the site to be counted.
 - This indicator can be used at the site level as the percentage of HIV service delivery points visited that have the most current edition of the national HIV testing guidelines and/or algorithms available.
- **Average percentage of a set of unexpired tracer commodities available at an HIV testing site**
 - The product is available if even one unit of unexpired product is in stock in the HIV testing site storage area.

- Ask for the inventory record or stock card for each tracer product, and check if there is unexpired stock available for each item.
- At national or program level, the indicator is calculated for a set of sites by summing up the average percentage of a set of products available for each site and dividing this figure by the number of sites counted.
- **Average percentage of stock records that correspond with physical counts for a set of tracer commodities in an HIV testing site**
 - Ask for the stock card showing the current stock level for each tracer commodity and check the level against stock held on the shelf.
 - At national or program level, the indicator is calculated for a set of sites by summing up the average percentage of stock records that correspond with physical counts for each site and dividing this figure by the number of sites counted.

Assuring the Quality of HIV Testing Commodities and the HIV Testing Process

It is important to incorporate quality assurance procedures into HIV testing commodity supply systems to ensure that each product is safe, effective, and of standard quality. A comprehensive quality assurance program cuts across the four primary components of the commodity management cycle and ensures that—

- HIV test kits, medicines, and other commodities are selected on the basis of safety and efficacy or performance
- Manufacturers meet acceptable performance standards—known as GMPs—which include criteria for personnel, facilities, equipment, materials, manufacturing operations, quality control, labeling, and packaging
- Sources are recognized as trusted suppliers of good-quality products and operate a reliable service to ensure that commodities meet specified quality standards at the time of delivery
- Quality of commodities is not compromised during storage or transportation
- Recall procedures are implemented to remove defective products

In addition, program and laboratory managers should establish a comprehensive laboratory quality system program that includes policies, and quality assurance, quality control, and quality improvement of the products, equipment, and HIV testing procedure. Practical guidance for establishing quality management systems is available.³⁰

³⁰ WHO/U.S. Department of Health and Human Services/CDC/U.S. Global AIDS Coordinator. 2005. *Guidelines for Assuring the Accuracy and Reliability of HIV Rapid Testing: Applying a Quality System Approach*. Geneva: WHO. http://www.who.int/diagnostics_laboratory/publications/guidance/en/index.html.

Quality system considerations include³¹—

- At the point-of-service level, assigning responsibility for managing the quality system program to a “quality officer” who should ensure that all components of the quality system are in place before testing can begin at the point of service. All HIV testing should be performed by staff that are trained and certified to national standards or meet national requirements where no certification exists.

- Quality control procedures should be in place to measure the performance of an individual test or reagent when it enters the system and every time it is used. Internal controls, usually built into the testing device of rapid HIV test kits or sometimes provided separately, are run with every test. Because internal controls do not evaluate the entire testing process, external controls using positive, weakly positive, and negative controls are run periodically to assure that test kits are detecting HIV antibodies accurately.

HIV Rapid Tests: Running External Quality Controls

The MoH should develop a policy outlining the frequency and criteria for running external quality controls, depending on the local context, including environmental conditions. WHO/CDC^a recommend that one positive and one negative control (and weakly positive when possible) should be run as follows—

- At least once a week, preferably at the beginning of the week
- When a new operator (newly trained or who has not been testing for a while) starts performing tests
- When using a rapid test kit with a new lot number
- When a new shipment of the test kit is received
- If kits have been exposed to environmental conditions that are not in line with the manufacturer’s recommendations

a. WHO/U.S. Department of Health and Human Services/CDC/U.S. Global AIDS Coordinator. 2005. *Guidelines for Assuring the Accuracy and Reliability of HIV Rapid Testing: Applying a Quality System Approach*. Geneva: WHO. http://www.who.int/diagnostics_laboratory/publications/guidance/en/index.html.

- Internal quality assurance procedures include monitoring of the “cold chain”—for example, monitoring the temperature of storage refrigerators for both HIV tests and specimens—and checking expiration dates of kits and reagents. Written SOPs should be in place and accessible to all staff for training staff on the HIV testing algorithm used, laboratory safety, drawing blood, handling and labeling specimens, testing, and recording and reporting results.
- External quality assessment methods to evaluate the performance of points of service include proficiency testing, retesting of specimens, and on-site monitoring. See the publication *Guidelines for Assuring the Accuracy and Reliability of HIV Rapid Testing*:

³¹ Ibid.

*Applying a Quality System Approach*³² for advantages and disadvantages of each quality assessment method for points of service using rapid HIV test kits and for further information on quality assurance of HIV rapid testing. Often, on-site monitoring by a knowledgeable team using a checklist³³ is particularly helpful for low-volume points of service. As mentioned earlier, integrating selected commodity management parameters into this checklist is one approach for using existing systems to monitor the performance of the commodity management system for HIV counseling and testing programs.

Using Quantification Data to Monitor the Use of Rapid HIV Test Kits

Data collected for quantifying procurement needs at the national or program level can yield useful information about how rapid HIV test kits and other supplies are being used at sites. Comparing actual consumption data of screening and tiebreaker tests, percentage of tests used for quality control or percentage wasted, and the percentage of discordant results either with expected results or between sites can identify sites with unusual usage patterns or cross-program discrepancies that need to be investigated further.

For example, in one country, when calculating needs for an emergency procurement, the quantification team noticed that sites were reporting very different data on the percentage of discordant results. Possible causes of the discrepancies included incorrect use of the confirmatory test, inexperience in interpreting test results, and quality problems with either the screening or confirmatory test. The quantification team informed the program managers of the discrepancies and investigations are ongoing.

Source: MSH/RPM Plus.

³² Ibid.

³³ Appendix H of the following document has an example of an on-site monitoring checklist that includes commodity management issues: WHO/U.S. Department of Health and Human Services/CDC/U.S. Global AIDS Coordinator. 2005. *Guidelines for Assuring the Accuracy and Reliability of HIV Rapid Testing: Applying a Quality System Approach*. Geneva: WHO. http://www.who.int/diagnostics_laboratory/publications/guidance/en/index.html.

COMMODITY MANAGEMENT FOR TAKING HIV COUNSELING AND TESTING PROGRAMS TO SCALE

Coordinating Responses and Establishing Linkages to Other Prevention and Care Services

Over the last few years, an unprecedented increase has occurred in commitment, effort, and resources by national governments, UN agencies, donors, and international and local NGOs to improve access to HIV counseling and testing in the most affected countries. The increased interest in improving health care and funding for treatment and prevention services, and HIV counseling and testing programs as an entry point to them, has generated a number of significant global initiatives that are working to address challenges. These efforts include WHO's Universal Access Initiative, the Global Fund, and PEPFAR. Such global initiatives, coupled with local approaches for expanding the range of service delivery models, have in turn increased the number of partners financing and implementing HIV counseling and testing programs in countries.

Partnership with and collaboration among national government, NGOs, community-based organizations (CBOs), the private sector, UN agencies, and international donor agencies have been shown to be effective in strengthening the commodity management system for HIV counseling and testing. However, experience has shown that to be successful, a process needs to be established to facilitate coordination, communication, and collaboration; this process should include all stakeholders. Identifying the key stakeholders and mapping their roles in providing or supporting HIV counseling and testing programs is an important first step.

Donors play a significant role in supporting the implementation of HIV counseling and testing programs, including financing and procuring commodities and helping national governments scale up their services. But not all the results of donor support have been positive. Difficulties have occurred in the past when donors helping to finance or provide commodities required special accounting practices for their products along with different preconditions, delivery schedules, and procedures. More recently, donors have played a role in bringing stakeholders to the table to coordinate roles and facilitate collaboration to strengthen HIV counseling and testing services.

As national governments move forward with scaling up PITC, an increasing number of departments and clinical programs within the ministry of health—for example the TB program, maternal and child health services, and the STI program—are incorporating HIV counseling and testing as part of their service package. Mapping the activities of government departments and programs is an important step to facilitate joint work planning and budgeting to maximize efficiency in commodity management and capacity-building activities.

In developing countries, many of the most successful VCT programs are operated by NGOs and CBOs that procure and manage their own supplies. But because staff responsible for these activities often have little or no experience or training in commodity management, they experience difficulties in managing stocks and accurately quantifying requirements, particularly when planning to scale up programs. Stand-alone units are not able to benefit from the

economies of scale by buying kits and supplies in bulk, and they lack access to information on suppliers and sources. Some countries have experienced difficulties in setting up management information systems to collect data on HIV testing in NGO facilities, which is vital for forecasting needs when supplies such as HIV test kits are procured centrally. NGO and CBO staff may not know where to refer clients for other services. Ensuring that implementing NGOs and CBOs are covered in the mapping process and remain included in the decision-making process to strengthen commodity management systems is key to planning and implementing appropriate interventions to address the specific needs of these implementing organizations.

Key questions include—

- Which people or organizations are already involved in providing or supporting national and local HIV counseling and testing programs?
- How are HIV counseling and testing services funded? Who provides funding for what, and how much?
- Which service delivery models are used for HIV counseling and testing, including stand-alone, integrated, and mobile services? Who uses the existing services? What is the demand for existing services?
- What commodities do existing HIV counseling and testing programs need? How are they selected? Where do they come from?
- Which organizations are involved in HIV counseling and testing commodity management, including selection, procurement, distribution, and use? Who develops and implements policies and procedures at the national and local levels? Who is responsible for developing and enforcing legislation and regulation for HIV counseling and testing services?
- Who is responsible for developing and implementing external quality assurance monitoring of HIV testing? How are quality assurance programs funded, and how effective are they?
- What technical and commodity management training is provided, and who provides it?
- How is commodity management information and data collected, analyzed, used, and shared?

Similar questions may need to be asked at larger facilities to map which clinics, departments, and in-patient services offer HIV counseling and testing services; where in the facility HIV testing is done and by whom; and what procedures are in place for quality assurance. It is important to establish how the HIV testing commodities are funded, where they come from, and where they are stored and issued to.

Establishing a process to bring stakeholders to the table to improve coordination can help—

- Identify gaps and duplication

- Allow stakeholders to build on their relative strengths
- Identify successes to build on
- Identify opportunities for streamlining and harmonizing roles and approaches
- Strengthen linkages between programs and set up systems for referring clients for other services
- Plan for collaborative action to strengthen commodity management systems—clear and agreed upon roles and responsibilities for partners and collaborators are vital

Where possible, existing structures and mechanisms for coordination should be used to avoid duplication. For example, the national or facility committee in place for coordinating the scale-up of antiretroviral programs could establish a separate subcommittee or alternatively hold additional meetings to address HIV counseling and testing issues with an expanded membership as appropriate. Several countries have identified a team or working group that is specifically responsible for coordinating the financing, procurement, and distribution of HIV testing commodities and often other HIV-related medicines and supplies. The roles and responsibilities of the team usually include—

- Quantifying needs and budgets by program for a procurement period; preparing one-to-two-year forecasts for resource mobilization
- Identifying barriers to the quantification process and providing recommendations on how to address them; collecting information on issues that may affect consumption patterns
- Overseeing procurement processes and aligning procurements with disbursements
- Developing and implementing procurement and distribution plans; regularly reviewing consumption and the rate of scale-up and adjusting procurement and distribution quantities accordingly
- Tracking disbursements and mobilizing emergency funding if disbursements are delayed
- Supporting efficient data collection, analysis, and reporting by points of service

HIV counseling and testing is an entry point to a range of HIV prevention, care, and treatment services, and new service delivery models are being introduced and PITC expanded to facilitate access to these services. In many cases, however, the package of services that can and will be offered at HIV counseling and testing service delivery points, whether integrated, stand-alone, or mobile has not been defined, services that do exist are limited, and essential medicines and commodities are often unavailable. In addition, staff often lack the information or systems in place to refer clients for other services. Both at the national and point-of-service levels, program planners and managers need to define the package of interventions that will be offered at HIV counseling and testing service delivery points and formalize linkages, referral systems, and networks to other services. This step will in turn allow supply managers to develop a comprehensive commodity management strategic plan for funding, procuring, and distributing

adequate quantities of HIV-related commodities, medicines, and supplies where they are needed and when they are needed.

Rationalizing Commodity Management Systems for HIV Counseling and Testing

In countries where commodity management systems are weak and HIV counseling and testing has been identified as a priority, program managers and particularly donors not uncommonly have established separate vertical supply systems for HIV testing commodities as a short-term fix. Few donors or planners, however, have developed a strategy for integrating a vertical supply system into the overall commodity management system in the long term or recognized that rationalizing multiple parallel supply systems is ultimately complex, time-consuming, and costly. As a result, many point-of-service staff are burdened with managing separate ordering, storage, and reporting systems and not infrequently borrow from one program for another to fill gaps. At the central level, fragmented financing, procurement, and information management systems make it difficult for program managers to forecast and budget needs for scaling up services in the long term and to manage supply problems in the short term.

As mentioned earlier, a number of national governments and their partners are now working to rationalize multiple, vertical procurement and supply systems. Establishing a coordinating mechanism that includes all stakeholders is an important first step, because it provides a forum for raising awareness on the disadvantages of the current situation and to encourage partners to begin discussions and identify and address constraints to integrating systems. Strategies for integration are country and context-specific but very often begin with standardizing data collection tools and reporting systems, and structures for commodity management. Governments and partners in several countries are now moving forward with mapping out a process to integrate distribution initially, and later procurement, very often into an existing system for essential medicines or laboratory supplies or both. The process should ideally be incorporated into a comprehensive strategic plan for commodity management to ensure that each phase of integration is aligned with the necessary capacity building of people, systems, and structures.

Planners of HIV counseling and testing pilot programs, such as mobile services, should develop a commodity management strategy. Consideration should be given to where supplies will come from and when commodities will be procured or supplied by a donor or a donor-funded agency. If the pilot program is eventually to be handed

Rwanda: Case Study on Integrating Commodity Management Systems

Prior to 2006, each of the implementers of HIV counseling and testing programs had quantified needs, procured kits, and stored rapid HIV test kits independently from one another. In 2006, the partners began to explore using the Coordinated Procurement and Distribution System established for antiretroviral medicines to procure and distribute HIV test kits. The national public sector drug procurement and supply agency, Centrale d'Achat de Médicaments Essentiels du Rwanda (CAMERWA) is responsible for procuring and distribution HIV test kits with Global Fund grants. As a first step to integration, the implementers funded by PEPFAR will integrate storage and supply of their individually procured supplies at CAMERWA. A proposal is being drafted to integrate distribution for all partners at CAMERWA.

Source: MSH/RPM Plus.

over to the local government or a local organization, the strategy should address where the commodities will come from in the long term and how they will be funded.

Planning for Going to Scale

In recent years, as national governments and program managers have moved to scale up HIV counseling and testing services, commodity management systems have struggled to support the exponential expansion, especially in high-burden countries. As mentioned earlier, as countries plan for universal access, it is important to recognize that the level of projected scale-up will challenge even those systems that are currently working well. For example, in Kenya, data submitted to the MoH shows that the number of people receiving VCT increased from 110,000 in 2002 to 545,000 in 2005,³⁴ roughly translating to a fivefold increase in three years in the quantity of HIV screening test kits and reagents that have to be procured, stored, and distributed. It is therefore essential that program planners and managers develop a comprehensive strategic plan for commodity management that addresses both commodity procurement and capacity building of systems to properly manage them.

Clearly defining the goals for scaling up HIV counseling and testing and the package of services at both the national and point-of-service levels is an important first step to ensure that the management and supply of commodities appropriately supports those goals. The next step is to assess the existing commodity system for HIV counseling and testing to identify the strengths, gaps, and challenges to expansion. Many of the challenges will be context or country-specific. It is useful to consider the system as a whole to identify areas for improvement, including major bottlenecks and origins of problems that can appear in several different parts of the system. Next, identify ways to address the areas that need improvement, and target specific areas for the greatest impact and develop a multiyear plan. The plan should incorporate a financing strategy and ensure that capacity-building activities are aligned with strategies to integrate commodity management systems into existing systems for essential medicines or laboratory supplies and other health sector capacity-building activities. Consensus and partnership among international and multilateral capacity-building organizations to facilitate a unified approach in providing technical support for strengthening HIV counseling and testing services in resource-constrained countries should be encouraged as much as possible.

³⁴ E. Marum et al. 2006. "Scale-up of Voluntary HIV Counseling and Testing in Kenya." *JAMA* 296 (9): 859–62.

Commodity Management Issues for HIV Counseling and Testing Service Delivery Models and Approaches

In this section, some of the commodity management considerations for supporting different service delivery models and approaches for HIV counseling and testing are outlined, including innovative interventions. Considerations are mainly based on experiences from pilots and operations research and are presented as an initial list (Table 3).

Table 3. Commodity Management Considerations for HIV Counseling and Testing Approaches and Service Delivery Models

HIV Counseling and Testing Approaches and Service Delivery Models	Commodity Management Issues
"Opt-in" and "opt-out" approaches to PITC	<ul style="list-style-type: none"> • Opt-out approaches significantly increase uptake of HIV testing compared to opt-in approaches. • Considerations when introducing an opt-out approach— <ul style="list-style-type: none"> ○ What additional quantity of HIV testing commodities will need to be budgeted for and procured? ○ Is the existing storage space adequate to store the additional kits and supplies? • Actual usage should be monitored over the initial start-up period and procurement and distribution quantities adjusted accordingly.
Parallel and serial approaches to testing with rapid HIV test kits	<ul style="list-style-type: none"> • Parallel testing uses more second (confirmatory) HIV test kits, and both first and second tests must be continuously available for HIV counseling and testing services to be offered. • Considerations when switching from serial to parallel testing— <ul style="list-style-type: none"> ○ What additional quantity of second (confirmatory) HIV tests kits and supplies will need to be budgeted for and procured? ○ Is the existing storage space adequate to store the additional kits and supplies? ○ Have all point-of-service-level staff been informed of the change in the testing algorithm? Have training materials, SOPs, and job aids been updated to reflect the change? • Considerations when switching from parallel to serial testing— <ul style="list-style-type: none"> ○ Have all point-of-service-level staff been informed of the change in the testing algorithm? Have training materials, SOPs, and job aids been updated to reflect the change? ○ Have staff responsible for quantifying needs and procuring HIV test kits been informed of the change in the testing algorithm? • When changing the testing strategy used, the actual usage should be monitored over the changeover period and procurement and distribution quantities adjusted accordingly.

HIV Counseling and Testing Approaches and Service Delivery Models	Commodity Management Issues
Stand-alone HIV counseling and testing sites	<ul style="list-style-type: none"> • These sites generally do not have dedicated staff for commodity management. <ul style="list-style-type: none"> ○ Do staff require training and user-friendly tools to enable them to properly manage commodities and complete reports? • They often need to use their own transport when collecting supplies. <ul style="list-style-type: none"> ○ Will safety stocks need to be increased to cover delays when transport is unavailable? ○ Can supplies be delivered directly to the site? ○ For kits that require refrigerated or cool storage, what equipment and supplies will be needed to maintain the cold chain during transportation? • Refrigerated or cool storage is often limited or unavailable. <ul style="list-style-type: none"> ○ Do sites need to order smaller quantities more frequently? • Risk of expiry of test kits, especially tiebreaker kits with low usage, is usually higher. <ul style="list-style-type: none"> ○ Do sites need a mechanism for exchanging short-dated stock and assistance with disposing of expired stock? • Offering other services that involve prescribing and dispensing of medicines may be problematic because of lack of qualified staff. <ul style="list-style-type: none"> ○ Do sites have information and system to refer clients for other services?
Health-facility-based HIV counseling and testing operating as a separate unit	<ul style="list-style-type: none"> • Considerations for stand-alone sites or integrated models may apply depending on the level of partnership between the clinic and the health facility.
Integrated model (co-located): VCT or PITC offered in medical settings	<ul style="list-style-type: none"> • Experiences show that establishing a multidisciplinary team facilitates integration of HIV counseling and testing into other services and coordination of efforts at the facility. • Consider including the procurement staff on the team and developing a commodity management plan, especially in facilities with multiple service delivery points. • Actual usage should be monitored over the initial start-up period, and budgets and procurement quantities adjusted accordingly. • Some questions for the team to consider include— <ul style="list-style-type: none"> ○ What quantity of HIV testing commodities will need to be budgeted for and procured? ○ Where will test kits come from, and where will they be stored? ○ Can supply management be integrated into an existing commodity management system? ○ Will HIV testing be performed at each service delivery point, or will clients be referred elsewhere at the facility? ○ Is space adequate to perform HIV counseling and testing at the clinic, and do staff have time to take on the additional responsibilities? ○ How will the quality of testing be assured? ○ What other services will be provided as part of the HIV counseling and testing package, and where will the associated medicines and supplies come from? ○ How will data on usage be collected and reported?

HIV Counseling and Testing Approaches and Service Delivery Models	Commodity Management Issues
Mobile or semi-mobile outreach VCT services that provide temporary and rotating services, using, for example, caravans, bicycles, and motorbikes	<ul style="list-style-type: none"> • Actual usage should be monitored over the initial start-up period and budgets and procurement quantities adjusted accordingly. • Considerations when setting up mobile services include— <ul style="list-style-type: none"> ○ Where will the kits and supplies come from? ○ What quantity of HIV testing commodities will need to be budgeted for and procured to support the services? ○ What equipment and supplies will be needed to store and transport the commodities appropriately to maintain quality? ○ How will the quality of testing be assured? ○ How will data on usage be collected and reported?
Community or home-based or family-based	<ul style="list-style-type: none"> • Considerations for mobile or outreach VCT services apply.
NGO and for-profit private sector	<ul style="list-style-type: none"> • If procuring alone, they may not benefit from economies of scale. Kits may be more expensive, and budgets will need to be adjusted accordingly. • They may not always be aware of or adhere to national testing guidelines • Where supplies come through the public sector, a mechanism for reporting to the central level may need to be established to avoid underreporting of usage.
National testing days and campaigns	<ul style="list-style-type: none"> • It can be helpful to develop a plan or a planning toolkit to promote coordination and to ensure that HIV test kits and other supplies are available in sufficient quantities where they are needed. • Some questions to consider include— <ul style="list-style-type: none"> ○ Have targets been set for the campaign to guide budgeting and procurement, and are they realistic? ○ What quantity of HIV testing commodities will need to be budgeted for and procured? What quantities are already in the procurement pipeline? ○ How will the kits be distributed to the points of service? ○ Where will the additional supplies of test kits be stored? ○ How will the quality of testing be assured? ○ How will data on usage be collected and reported? ○ Some additional demand for testing may be sustained after the campaign is over. What quantities of HIV testing commodities need to be budgeted for and procured to meet the additional demand?

Zambia VCT Services: A Case Study on Scaling Up

Zambia Voluntary Counseling and Testing Services was started at the University Teaching Hospital in Lusaka in the late 1990s, mainly with funding from the Norwegian Agency for Development Cooperation (NORAD). The objectives of ZVCTS were to coordinate the implementation of VCT services, train adequate numbers of VCT staff, review and harmonize HIV testing protocols, streamline information systems, improve tracking of specimens sent for testing, and continue research activities with the virology laboratory (which receives funding from the Japan International Cooperation Agency [JICA]). Other activities included coordinating activities with NGOs and CBOs that introduced VCT in Zambia and that still play a major role in VCT service delivery.

Zambia has scaled up its HIV counseling and testing services substantially since 1999; ZVCTS reports that the number of sites increased from 22 to 650 by the end of 2006. This expansion represents almost a 30-fold increase over seven years in the number of sites that the national commodity management system must order for and distribute HIV test kits to. The commodity management information system must in turn meet the challenge of collecting and consolidating data from 650 sites to inform quantification and procurement processes. Data reported by ZVCTS shows that the number of clients tested increased from 27,348 in 2002 to 337,760 in 2006, roughly representing a 12-fold increase in the volume of tests kits that needed to be stored and distributed in just four years. As can be seen in Figure 3, the rate of scale-up has not been constant; the number of new sites opening per year has fluctuated from 19 to 249. Good communication and coordination between program managers, commodity management staff, and partners supporting HIV counseling and testing has been key to success in achieving this level of expansion.

By the end of 2001, the number of VCT sites in Zambia had increased to 88, and the systems in place to procure, store, and manage HIV test kits and other supplies were quickly reaching capacity. ZVCTS management and stakeholders identified several strategies to support the further scaling up of VCT services—

- Review and harmonize HIV testing protocols.
- Train additional laboratory technicians.
- Conduct more training.
- Strengthen overall capacity of supply management systems.

In 2000, six different rapid HIV test kits were used in Zambia because of the lack of harmonization across donors and facilities. Some donated test kits were not included in the national HIV testing protocol or were inappropriate for the technical capacity and local situation. In 2001, after a thorough literature review and extensive consultation with kit users, stakeholders, and regional laboratory technicians, a testing protocol was adopted nationwide.

In 2001, two procurement procedures were used. For local, small-volume MoH procurements, ZVCTS quantified needs and solicited price quotations from wholesalers. Prices remained high because transactions often involved small quantities. Procurement of diagnostic kits and medical supplies was, until 2001, funded by NORAD, and payment was managed by WHO. Kits and supplies were procured directly from manufacturers or their agents. As funds from NORAD decreased, JICA stepped in to fill the anticipated gap. Unlike NORAD, JICA purchased products in bulk through a competitive bidding procedure managed by JICA headquarters in Tokyo. Therefore, the ZVCTS commodity management system had to quantify requirements for one order per year and identify sufficient storage space to hold the entire stock for two years. The virology department previously held and managed the stock of test kits and supplies, but it had insufficient storage space to hold even one year's supply of stock. Consequently, in 2001 the decision was made to integrate the VCT supply system into the national supply system and store stock at the Medical Stores Limited (MSL). ZVCTS remained in charge of distribution, but in most cases VCT facility managers had to collect their own supplies because transport was unavailable. Later in 2002, ZVCTS and MSL began work to integrate the distribution of HIV test kits and other supplies into the system used to deliver the Rural Health Centre Essential Drugs Kits every month.

In 2002, as part of its initiative to strengthen the management information system (see box in the chapter “Issues to Consider for Commodity Management for HIV Counseling and Testing Programs”), ZVCTS established a group that, with assistance from RPM Plus, worked to reach consensus on indicators and to coordinate data collection. This group evolved into the VCT Technical Working Group, a mechanism to facilitate coordination, communication, and collaboration among key stakeholders and players to harmonize roles and approaches. Over the years, new partners offering support to Zambia’s HIV counseling and testing programs have been invited to join the group. Although the number of stakeholders has increased substantially as of 2007, new initiatives and partners have largely integrated supply management of HIV test kits into the existing system managed by the MoH and distributed by MSL. The VCT Technical Working Group has worked hard to avoid fragmentation of HIV test kit procurement and distribution systems.

Over the last five years, the MoH, ZVCTS, and its partners have taken a number of steps to strengthen the capacity of the commodity management system to support the scale-up of HIV counseling and testing services to its current level. A national committee coordinates procurement and quantification of HIV test kits, with the MoH taking the lead on working with partners to quantify needs on an annual basis. In 2006, the agencies involved in procuring HIV test kits included JICA, which procures directly using its own funding; UNICEF, which procures kits on behalf of the government of Zambia with Global Fund monies and with the government using World Bank funding; CDC, which procures kits with PEPFAR funding; and the U.S. government-funded JSI/DELIVER project that procures kits with U.S. government funds.³⁵ In addition, Zambia obtains supplies of Determine™ HIV-1/2 test kits through the Axios Foundation for its PMTCT programs. Renovations are currently under way to create more storage space for HIV test kits and other commodities as part of the general renovations at MSL. The MoH has formed a new unit, the Logistics Management Unit, operating within MSL, to streamline HIV test kit distribution. Supplies are requisitioned from the facilities using a pull system, and MSL develops a distribution plan based on reports submitted by facilities. To cut down on the time taken to process orders, a ZVCTS staff member has been transferred to work with MSL to review and approve orders; requisitions no longer need to be sent to ZVCTS for approval.

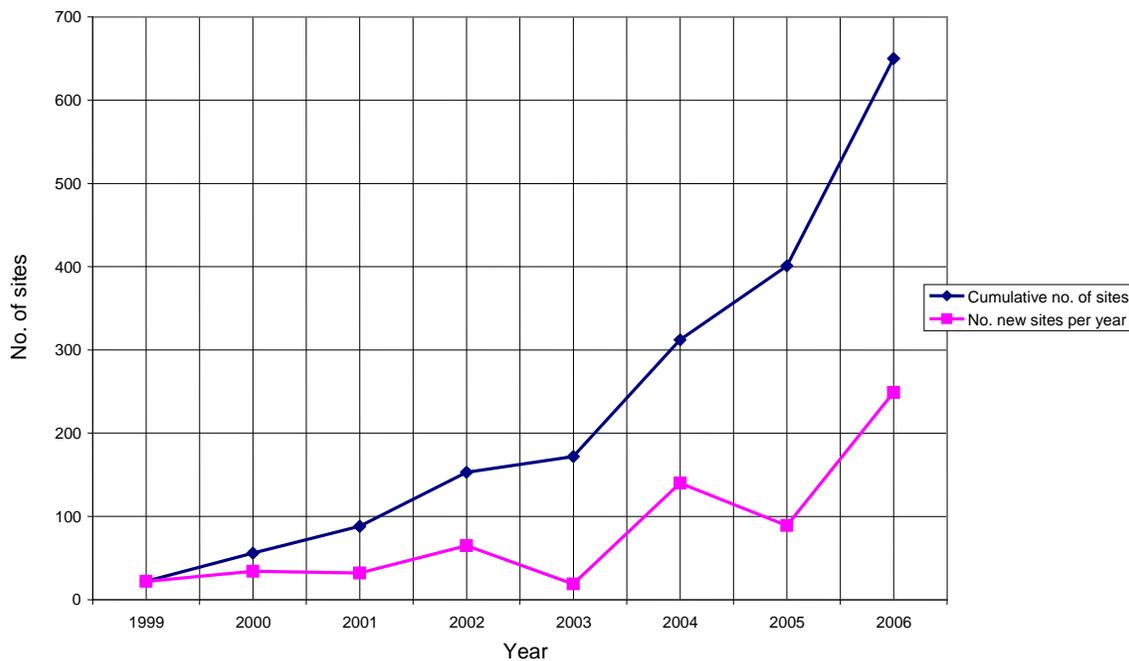
ZVCTS and the MoH recognized early on that capacity building at the district level is essential to support scale-up of HIV counseling and testing services and to sustain programs in the long term. Strategies to transfer technology and skills to the district level and to build local ownership began in 2002. A pull system for ordering was established early; tools were developed as part of the commodity management information system, and training has been ongoing so that staff are prepared to quantify their needs and prepare accurate reports. The information system is actually maintained at the district level; the district officer not only is responsible for aggregating data, and generating and forwarding reports to ZVCTS but also provides feedback to facilities on a monthly basis. This monthly report compares each site’s activities with other similar facilities and aims to motivate staff to maintain or improve their performance. Facilities no longer need to

³⁵ E. Hasselberg et al. 2006. *Procuring HIV/AIDS Commodities Using U.S. Government Funds*. Arlington, VA: DELIVER for USAID.

collect their supplies from MSL—MSL delivers directly to the district offices—and a long-established system exists for returning short-dated stock for redistribution.

In 2005, mobile HIV counseling and testing units began offering services in Zambia, and demand for services has been reported to be high, with some sites reporting that mobile counseling and testing services are contributing more than 50 percent of the clients tested. Building the commodity management capacity of districts has been key in supporting the rollout of this new service delivery model, because mobile units obtain their commodities from and report consumption to the district level. In 2006, a new national HIV testing algorithm was developed, evaluated, and approved. The Genie II HIV-1/HIV-2 test kit was replaced by Uni-Gold™ HIV because this test kit, unlike Genie II HIV-1/HIV-2, did not require refrigeration and was also easier to use. The process was inclusive and participatory with the National AIDS Council, the Zambia Prevention, Care and Treatment Partnership, the MoH, the VCT, and the PMTCT Technical Working Groups contributing to the process.

Although considerable progress has been made, an ongoing need exists to strengthen and build the capacity of the districts so they can undertake their emerging and expanding role, which includes supporting the expansion of new HIV counseling and testing service delivery models. Sustainability of the program is still donor dependent, and facilities that have direct support from partners are reported to fare somewhat better in terms of capacity-building activities than those without external support.



Source of data: ZVCTS 2007.

Figure 3. Growth of HIV Counseling and Testing Services in Zambia

COMMODITY MANAGEMENT CONSIDERATIONS FOR IMPLEMENTING CHANGES TO NATIONAL HIV TESTING GUIDELINES

As discussed earlier in this document, program planners and managers may elect to change national testing algorithms or guidelines for a number of reasons. New products entering the market may demonstrate improved performance, have longer shelf lives, or be significantly cheaper or easier to use, store, and transport. Products currently included in the guidelines may become unavailable, or the continuity of supply or quality of the product may become unreliable. Experience from malaria and TB control programs demonstrates that problems can result in the availability of products during the changeover period unless the implications for supply management are recognized and planned for. The commodity management considerations for implementing changes to national HIV testing guidelines or algorithms are outlined below.

Registration: In most countries, rapid HIV test kits are required to be registered with the national regulatory authority. Some countries may have a fast-track mechanism for registering products, but in others, this process can be lengthy and difficult. It is therefore critical that program managers work with manufacturers to initiate the process of registering products early.

Planning and budgeting: It is important to determine the first possible arrival date of the new HIV test kits and develop a plan for making the product available. Planners and program managers will need to decide whether the new HIV test kit will be phased in gradually, for example by geographical region or type of testing site, or introduced through a nationwide or programwide rollout. Funding will need to be identified for the update and dissemination of guidelines and other materials and for training activities. Other costs of the transition may include filling the pipeline, including buffer stocks, and withdrawal and incineration of obsolete kits. Any additional equipment or supplies that are needed to perform testing with the new HIV test kit will also need to be planned and budgeted for.

Revision of program guidelines and essential supply lists: In addition to updating the national HIV counseling and testing algorithm and guidelines, other program guidelines and tools may need to be updated. Training curricula and materials, laboratory manuals, SOPs, and job aids and tools may all need to be revised. Quality assurance checklists and tools will also have to be updated or adapted. In countries where a national essential supply list or essential medical device list is used to guide selection for national procurement, a request to include the new HIV test kit in the list will need to be submitted promptly.

Reporting and recording forms: The forms used by the HIV counseling and testing program will need to be revised to include the new product and then printed. Relevant changes to the commodity management information system and other forms used for ordering and managing supplies, for example, requisition forms, may also be required.

Dissemination of guidelines and training of health workers and community partners: It is important that training and sensitization activities of point-of-service staff are coordinated with distribution of products to the testing sites because staff may forget key messages if a long delay occurs between training and arrival of the new test kits.

Management of HIV test kits to be phased out: Program and supply managers will need to map the locations where stocks of the “old” test kits are held and compile accurate estimates of quantities in stock and in the supply chain. A plan for adjusting future procurements should be developed to ensure that when the switch to the new test kit is made, the system does not have a large stock of the obsolete test kits. The phasing-in/phasing-out process should be carefully monitored and the timing for phasing out of “old” products adjusted as necessary, for example, where deliveries of the new products are delayed. It is better to be left with some stocks of the obsolete products than to run out before the new HIV test kits arrive.

Forecasting and quantification: A critical step when planning for the transition to the new rapid HIV test kit is preparing a forecast of requirements to determine and justify a budget. Any budget restrictions or factors that may affect the forecast, such as procurement by other partners, will need to be identified, and the requirements for filling the pipeline, including buffer stocks at different levels, should be included in the estimate. Because the new HIV test kit will usually be replacing an existing product, initial forecasts can be based on the consumption of previously used kits. Any ancillary supplies that are needed for performing HIV testing with the new kit should also be included. Program managers will need to work closely with procurement staff to quantify needs for procurement for phased or nationwide implementation and set the schedule for quantifying ongoing needs.

Procurement: It is important to check on any donor and government restrictions for procuring the new HIV test kit before deciding on the procurement mechanism (see Financing section in the chapter “Issues to Consider for Commodity Management for HIV Counseling and Testing Programs”). When the estimated lead time and expected shelf life on arrival in-country are known, program managers and supplies staff can prepare a procurement and distribution plan. The procurement schedule for any ancillary supplies needed for testing will need to be synchronized with the estimated delivery date of the new test kits. Managers of the supply process must promptly communicate information on potential delays to the team responsible for managing the changeover.

Distribution: The distribution strategy should be developed as part of the transition plan and integrated into the overall distribution plan. It is important to ensure that all the products needed to use the new HIV test kit are addressed in the distribution plan. Resource needs, for example, for additional deliveries will need to be included in the budget. Even when the new products are in stock at the central medical store, distribution to the peripheral level can take two to four weeks or more. It is therefore important to submit the request for distribution well in advance to coordinate the arrival of the test kits with training of point-of-service staff. Again, information on any potential delays in distribution will need to be promptly communicated to the team managing the transition. It is expected that the new HIV test kit will have been selected on the basis of requiring less-stringent storage conditions or having a longer shelf life and so should not present any additional challenges in terms of inventory management.

Monitoring quality and performance: Mechanisms for documenting and communicating problems with the performance or quality of the new HIV test kit should be integrated into the existing systems for internal and external quality assessment.

RECOMMENDATIONS

Recommendations for National Governments (National AIDS Control Programs, HIV/AIDS Coordinating Bodies, and Supporting International Technical Agencies)

- Establish an inclusive process to facilitate coordination, communication, and collaboration among key stakeholders and players.
- Identify a subcommittee or working group to coordinate procurement, particularly quantification, and distribution of HIV counseling and testing commodities, including donations at the national level. Prepare one-to-two-year forecasts of commodity needs to inform resource mobilization.
- Develop an HIV counseling and testing commodity financing strategy as part of the overall national HIV/AIDS strategic plan. Consider all costs associated with procuring and managing supplies, including recurrent expenditures such as procurement fees or markups, and costs associated with shipping, importing, storing, and delivering the products. Also incorporate resource needs for capacity building and technical assistance. Ensure that consideration is given to how HIV counseling and testing services will link to or integrate with other programs and capacity-building efforts.
- Establish a national technical advisory group to develop and regularly update national guidelines or algorithms for HIV testing at referral, hospital, clinic-based, freestanding, and mobile sites and distribute them to counseling and testing points of service, NGO or CBO implementers, and donors. Ensure guidelines or algorithms include recommendations for the identification and testing of children and infants.
- Develop a plan to address commodity management issues associated with implementing changes to national HIV testing guidelines or algorithms.
- Develop written SOPs and job aids to inform and train staff on the HIV testing algorithm, laboratory safety, drawing blood, handling and labeling specimens, testing, recording and reporting results, and managing HIV testing commodities.
- Develop or update national standard treatment guidelines for prophylaxis and treatment of HIV/AIDS-related diseases and referral procedures, and distribute the guidelines to donors, HIV counseling and testing program planners, and implementers as appropriate. Update the national essential medicines or supplies list and formulary, if necessary, to include medicines listed on the standard treatment guidelines for HIV/AIDS-related illnesses, HIV test kits, and other related commodities.
- Assess training needs, including those for commodity management, and develop appropriate training materials and curricula for point-of-service staff.
- Establish a national external quality assessment scheme that includes all national and peripheral public health laboratories performing HIV testing. Provide guidance for

implementers to develop a comprehensive laboratory quality system program that includes policies and quality assurance, quality control and quality improvement of the products, equipment, and HIV testing procedures.

- Use existing procurement and distribution channels where available; if a vertical supply system is established to support a pilot program or as a short-term fix, develop a strategy for integrating the vertical system into the overall commodity management system.
- Develop country or organizational capacity, or both, for tendering and bulk procurement of commodities. Help procurement staff identify dependable, high-quality suppliers. Assist in managing the tender process, constructing and negotiating contract terms, and assuring product quality.
- Provide technical assistance or training or both for quantification of needs and supply management at the point-of-service level. Establish or strengthen the management information system to collect usage data for centralized procurement and distribution of HIV testing commodities. Apply strict criteria when constructing procurement bids for tenders to ensure continuity and prevent frequent product changes.
- Send copies of national standard HIV testing guidelines to donors and ask them to work with the committee or group responsible for coordinating procurement and quantification. Communicate needs to donors and let them know what has gone right or wrong with donations. Clarify who will be responsible for costs associated with handling, distributing, and reporting on the donated products.
- Develop and regularly update a distribution plan that details numbers and locations of HIV counseling and testing points of service served, quantities of commodities needed, and delivery schedules. Program managers and staff in charge of distribution should map out the location of planned new HIV counseling and testing points of service at least annually. Make distribution systems more flexible and responsive by establishing procedures to allow point-of-service staff to order more frequently, place nonroutine orders, and return excess stock or stock close to expiry.
- Develop a policy on the safe disposal of expired stock and other medical waste and consider whether assistance is required at the national level to dispose of expired stock.
- Provide technical assistance to identify the strengths, gaps, and challenges in the existing HIV testing commodity system, particularly for scaling up or expansion. Work with planners and implementers to address areas for improvement and target specific areas for the greatest impact. Assist organizations and service delivery points in identifying indicators and strengthening data collection systems and supervisory processes to monitor the performance of the commodity supply system.

Recommendations for Donors

- Help countries develop a national long-term strategic plan for scaling up HIV counseling and testing services that includes a commodity financing strategy. Identify appropriate activities to fund or support.
- Fund and facilitate appropriate technical support to strengthen HIV testing commodity management. Ensure that support or implementation conforms and harmonizes with established in-country policies and procedures.
- Support the development and regular update, printing, and dissemination of national guidelines or algorithms for HIV testing.
- Ensure that donor-financed HIV test kits and other commodities harmonize with national guidelines and standard treatment guidelines.
- Use existing procurement and distribution channels when available. If a vertical supply system is established to support a pilot program or as a short-term fix, develop a strategy for integrating the vertical system into the overall commodity management system for the long term.
- Help countries establish an inclusive process to facilitate coordination, communication, and collaboration between key stakeholders and players.

Recommendations for HIV Counseling and Testing Implementing Agencies (Government, NGOs, CBOs)

- Develop a long-term strategic plan, including a commodity financing strategy for HIV counseling and testing services, and consider how such services link or integrate with other programs, points of service, or organizations. Ensure that the plan is in line with national policies and plans.
- For sites with multiple points of service for HIV counseling and testing, establish or use an existing facility team to facilitate coordination and communication and referral between different programs and services.
- Assess community demand for services to guide what is included in an HIV counseling and testing package. Establish linkages with other departments, organizations, or service providers who are better placed to provide certain services.
- Develop a directory of care and support services to facilitate referrals within the service area of each site. Ensure that HIV counseling and testing service providers are familiar with and, when possible, have established working relationships with referral departments and agencies in the directory.

- Ensure that updated national HIV testing guidelines and algorithms and appropriate standard treatment guidelines are available at HIV counseling and testing sites and available for all staff who are required to adhere to them.
- Adapt existing national SOPs where they exist, or develop point-of-service-based written SOPs and job aids to guide and train staff on the HIV testing algorithm, laboratory safety, drawing blood, handling and labeling specimens, testing, recording and reporting results, and managing HIV testing commodities.
- Assess training needs of staff, including commodity management and safe handling of specimens and HIV test kits, and provide updates on new tests or procedures. Monitor and evaluate staff skill levels as programs expand or new interventions are introduced.
- Ensure that points of service develop a comprehensive laboratory quality system program that includes policies and quality assurance, quality control and quality improvement of the products, equipment, and HIV testing procedure.
- Establish a management information system to collect usage data for centralized procurement of HIV testing commodities. Assess training needs in quantification.
- Ensure that point-of-service staff are familiar with relevant policies and legislation, including the national HIV testing policy, the national medicines policy, medicine and commodity legislation and regulation, and legal aspects of commodity procurement. Verify that points of service comply with legislation that controls the supply, storage, prescription, and dispensing of medicines when planning to introduce interventions that require medicines as part of the HIV counseling and testing package.
- Prepare a VEN analysis to decide how to spend budget funds if not enough funds are available to pay for everything and to establish priorities for procurement if storage space is limited.
- Use recognized and trusted suppliers that provide good-quality products and operate reliable services. Establish a commodity tracking system to monitor how much and when to order. Try to rationalize procurement and supply systems to keep transportation and administrative costs down.
- Assess existing HIV testing commodity systems to identify strengths, gaps, and challenges. Identify strategies to address areas that need improvement, and target specific areas for the greatest impact.

ADDITIONAL RESOURCES

For a complete overview of managing medicine and health commodity supply systems, including step-by-step approaches on managing pharmaceutical systems effectively:

Management Sciences for Health and World Health Organisation. 1997. *Managing Drug Supply*. 2nd ed. West Hartford, CT: Kumarian Press. (Available from Kumarian Press, ISBN #: 1-56549-047-9, <http://www.kpbooks.com>. Available at a reduced price for developing countries.)

For more information on managing the supply chain for HIV/AIDS programs:

DELIVER. 2006. *Guidelines for Managing the HIV/AIDS Supply Chain*. Arlington, VA: DELIVER for the U.S. Agency for International Development.

For information on establishing referral networks:

Family Health International. 2005. *Establishing Referral Networks for Comprehensive HIV Care in Low-Resource Settings*. Arlington, VA: FHI. (Available at <http://www.fhi.org>.)

For more information on PITC:

WHO/UNAIDS. 2007. *Guidance on Provider-Initiated HIV Testing and Counselling in Health Facilities*. Geneva. WHO. (Available at <http://www.who.int/hiv/en/>.)

For information on HIV test kits and guidelines on selecting HIV test kits and developing an HIV testing algorithm:

WHO/CDC/Association of Public Health Laboratories. 2003. *Guidelines for Appropriate Evaluations of HIV Testing Technologies in Africa*. Atlanta: CDC; 2003. (Available online at http://www.who.int/diagnostics_laboratory/publications/guidance/en/index.html.)

UNAIDS/WHO. 2004. *HIV Assays: Operational Characteristics (Phase 1), Report 14 Simple/Rapid Tests*. Geneva: UNAIDS/WHO. (Available online at http://www.who.int/diagnostics_laboratory/publications/hiv_assays_rep_14.pdf.)

WHO. 2004. *Rapid HIV Tests: Guidelines for Use in HIV Testing and Counseling Services in Resource-Constrained Settings*. Geneva. WHO. (Available online at <http://www.who.int/hiv/pub/vct/rapidhivtests/en/>.)

UNAIDS/WHO. 1997. "Revised Recommendations for the Selection and Use of HIV Antibody Tests." *Weekly Epidemiological Record* 72 (12): 81–87. (Available online at http://www.who.int/diagnostics_laboratory/publications/guidance/en/index.html.)

For more information on selecting testing technologies for early HIV diagnosis in infants and children:

WHO. 2007. "Early Detection of HIV Infection in Infants and Children: Guidance Note on the Selection of Technology for Early Diagnosis of HIV in Infants and Children." (Available from http://www.who.int/hiv/paediatric/EarlydiagnostictestingforHIVVer_Final_May07.pdf.)

For more information on quality assurance of HIV rapid testing:

WHO/U.S. Department of Health and Human Services/CDC/U.S. Global AIDS Coordinator 2005. *Guidelines for Assuring the Accuracy and Reliability of HIV Rapid Testing: Applying a Quality System Approach*. WHO: Geneva. (Available online at http://www.who.int/diagnostics_laboratory/publications/guidance/en/index.html.)

For information on the WHO Bulk Procurement Scheme:

Go to http://www.who.int/diagnostics_laboratory/en/. Follow the links to Bulk Procurement Scheme.

For information on UNICEF Procurement Services:

Go to <http://www.unicef.org/supply/>.

For information on UNFPA Procurement Services:

Go to <http://www.unfpa.org/procurement/>.

For information on ordering through SCMS:

Go to <http://scms.pfscm.org/scms>.

For information on sources and prices of HIV test kits:

UNICEF/UNAIDS/WHO/MSF. 2005. *Sources and Prices of Selected Medicines and Diagnostics for People Living with HIV/AIDS*. 6th edition. Geneva: WHO. (Available online at http://www.who.int/diagnostics_laboratory/publications/procurement/en/index.html.)

Management Sciences for Health in collaboration with the World Health Organisation. 2007. *International Drug Price Indicator Guide*. Arlington, VA: MSH. (Available online at <http://erc.msh.org/mainpage.cfm?file=1.0.htm&module=DMP&language=English>.)

Management Sciences for Health/Rational Pharmaceutical Management Plus Program. 2008. *HIV Test Kits Listed in the USAID Source and Origin Waiver: Procurement Information Document*. 4th edition. (Available online at <http://www.msh.org/projects/rpmpplus/WhatWeDo/HIV-AIDS/Test-Kits-Procurement.cfm>.)

For more information on planning and budgeting for scale-up:

Helpfenbein, S., and C. A. Severo. 2004. *Scaling up HIV/AIDS Programs: A Manual for Multisectoral Planning*. Boston, MA: MSH.

ANNEX A: QUANTIFICATION OF HIV TEST KIT REQUIREMENTS FOR HIV COUNSELING AND TESTING PROGRAMS

Terminology

HIV Tests

The first HIV test performed is called the *screening* test, the second the *confirmatory* test, and the third the *tiebreaker*. This terminology is used for both parallel and serial testing, although in parallel testing the screening test and confirmatory test are performed at the same time.

Parallel versus Serial Testing

Quantification of HIV test kit requirements for parallel testing differs from that for serial testing. In parallel testing, two screening tests are performed at the same time on every specimen. In serial testing, only those specimens that have a positive result on the first screening test are tested with the second, or confirmatory, test. Consequently, the number of confirmatory tests used in parallel testing is much higher than the number used in serial testing. Although parallel testing may offer certain advantages over serial testing, these must be balanced against the significantly higher cost of parallel testing.

Methodology

This section is intended to help point-of-service-level staff calculate the quantity of tests to order. Quantification of test kits for large centralized facilities or reference laboratories, and calculation of requirements to “fill the pipeline” (e.g., to fill shelves at each facility level) are not considered here. The first step in calculating how much to order is to calculate or estimate monthly usage for each type of HIV test kit. Monthly usage can be estimated by the morbidity method using demographic data or service statistics data, or by the usage (consumption) method. New programs will not have existing records, which are needed for the usage (consumption) method, but can use the adjusted usage (consumption) method as an alternative.

Calculation of Monthly Usage (U_m) Using the Morbidity Method and Demographic Data

This method uses information on population coverage, or demand, and HIV prevalence to estimate monthly usage. The information needed to use this method is summarized in Table A-1.

Table A-1. Information Needed to Use the Morbidity Method and Demographic Data

Information Needed	Why and Where to Get the Information
Number of clients who will receive HIV counseling	<ul style="list-style-type: none"> • New programs need to estimate the demand for HIV counseling and testing. Existing programs that target similar populations should be able to assist in estimating initial demand. • Ongoing programs should be able to estimate demand from existing records, although adjustments may need to be made for anticipated increases or decreases in demand.
Percentage of clients counseled that accept an HIV test	<ul style="list-style-type: none"> • New programs need to estimate the percentage of clients that will accept an HIV test after counseling. “Opt-out” approaches have been shown to result in higher uptake than “opt-in” approaches. Existing programs that target similar populations should be able to assist in estimating initial demand. • Ongoing programs should be able to estimate demand from existing records, although adjustments may need to be made for anticipated increases or decreases in demand. Adjustments will also need to be made if switching from an “opt-in” to an “opt out” approach or vice versa.
HIV prevalence in the population served (%)	<ul style="list-style-type: none"> • This information is used to calculate confirmatory test requirements for serial testing only. • Information on prevalence rates can be obtained from the national AIDS program, prenatal screening, and surveillance programs. National HIV prevalence may not be the same as the prevalence in the population served. • Ongoing programs should keep records to inform calculations of prevalence and monthly usage of confirmatory tests.
Discordant results (%)	<ul style="list-style-type: none"> • This information is used to calculate requirements for the tiebreaker test. • A <i>discordant result</i> is when the result of the screening test differs from the result of the confirmatory test for the same specimen, requiring a tiebreaker test. • For new programs, consult the national AIDS program, the national testing laboratory, or other programs using the same testing algorithm for estimates. • Ongoing programs should keep records to inform calculations of discordance and monthly usage of tiebreaker tests.
Number of tests used for quality assurance	<ul style="list-style-type: none"> • WHO/CDC recommend that one positive and one negative control should be run as follows³⁶— <ul style="list-style-type: none"> ○ At least once a week, preferably at the beginning of the week ○ When a new operator (newly trained or who has not been testing for a while) starts performing testing ○ When using a rapid test kit with a new lot number ○ When a new shipment of the test kit is received ○ If kits have been exposed to environmental conditions that are not in line with the manufacturer’s recommendations Additional controls may be required by the agency supervising quality assurance. • For new programs, consult the national AIDS program, the national testing laboratory, or other programs using the same testing algorithm for estimates. • Ongoing programs should keep records of stock used for quality assurance purposes to guide quantification.

³⁶ WHO/U.S. Department of Health and Human Services/CDC/U.S. Global AIDS Coordinator. 2005. *Guidelines for Assuring the Accuracy and Reliability of HIV Rapid Testing*. WHO: Geneva.

Information Needed	Why and Where to Get the Information
Wastage	<ul style="list-style-type: none"> No matter how careful and experienced the operator is, a certain number of tests will be wasted because of mishaps, and some tests will need to be repeated, when results are indeterminate. Wastage may decrease over time as staff become more experienced or may increase when new staff are trained. Needs for training can be included in wastage, but losses caused by expiring stock cannot. If no information is available, new programs can add 10 percent to requirements to account for wastage. Wastage should be monitored in ongoing programs to assist in quantification and evaluation of testing expertise.

Calculation of monthly usage (U_m) for serial and parallel testing using the morbidity method and demographic data is presented in Table A-2.

Table A-2. Calculation of Monthly Usage with the Morbidity Method and Demographic Data

Serial Testing	Calculation of Monthly Usage (U_m)
Number of clients estimated to accept HIV testing per month	= Number of clients estimated to receive HIV counseling per month multiplied by the percentage of clients counseled estimated to accept an HIV test
Monthly usage of first (screening) test	= Number of clients estimated to accept an HIV test per month plus monthly quality assurance requirements plus monthly wastage
Monthly usage of second (confirmatory) test	= Number of first (screening) tests needed per month for specimen testing multiplied by HIV prevalence (%) To the answer add monthly quality assurance requirements plus monthly wastage
Monthly usage of third (tiebreaker) test	= Number of second (confirmatory) tests needed per month for specimen testing multiplied by discordance (%) To the answer add monthly quality assurance requirements plus monthly wastage
Parallel Testing	Calculation of Monthly Usage (U_m)
Number of clients estimated to accept HIV testing per month	= Number of clients estimated to receive HIV counseling per month multiplied by the percentage of clients counseled estimated to accept an HIV test
Monthly usage of first (screening) test	= Number of clients estimated to accept an HIV test per month plus monthly quality assurance requirements plus monthly wastage
Monthly usage of second (confirmatory) test	= Number of clients estimated to accept an HIV test per month plus monthly quality assurance requirements plus monthly wastage
Monthly usage of third (tiebreaker) test	= Number of clients estimated to accept an HIV test per month multiplied by discordance (%) To the answer add monthly quality assurance requirements plus monthly wastage

Example 1: Calculation of monthly usage (U_m) using the morbidity method and demographic data

A new VCT program estimates 520 clients per month will come for testing from a population where HIV prevalence is estimated to be 30 percent and that 96 percent of clients will accept an HIV test after counseling. Requirements for quality assurance testing are estimated to be an additional 10 percent for the screening test, 10 percent for the confirmatory test, and 100 percent for the tiebreaker test. Wastage is estimated to be 10 percent for all three tests. Discordance is estimated to be 2 percent. See Table A-3 for calculations.

Table A-3. Example of Morbidity Method Calculations Using Demographic Data

Serial Testing	Monthly Usage (U_m)
Number of clients estimated to accept HIV testing per month	= Number of clients estimated to receive HIV counseling per month multiplied by the percentage of clients counseled estimated to accept an HIV test $= 520 \times 96\% = 499.2$ clients Round up to 500 clients
Monthly usage of first (screening) test	= Number of clients estimated to accept an HIV test per month plus monthly quality assurance requirements plus monthly wastage $= 500 + (500 \times 10\%) + (500 \times 10\%) = 500 + 50 + 50 = 600$ tests (Note that 500 tests are needed for testing specimens and that this figure is used for calculating the monthly usage of the second [confirmatory] test below.)
Monthly usage of second (confirmatory) test	= Number of first (screening) tests needed per month for specimen testing multiplied by HIV prevalence (%) To the answer add monthly quality assurance requirements plus monthly wastage From above, 500 first (screening) tests are needed per month for specimen testing $= 500 \times 30\% = 150 + (150 \times 10\%) + (150 \times 10\%) = 150 + 15 + 15 = 180$ (Note that 150 tests are needed for testing specimens, and this figure is used for calculating the monthly usage of the third [tiebreaker] test below.)
Monthly usage of third (tiebreaker) test	= Number of second (confirmatory) tests needed per month for specimen testing multiplied by discordance (%) To the answer add monthly quality assurance requirements plus monthly wastage From above, 150 second (confirmatory) tests are needed per month for specimen testing $= 150 \times 2\% = 3 + (3 \times 100\%) + (3 \times 10\%) = 3 + 3 + 0.3 = 6.3$ Round up to 7 tests

Parallel Testing	Monthly Usage (U_m)
Number of clients estimated to accept HIV testing per month	= Number of clients estimated to receive HIV counseling per month multiplied by the percentage of clients counseled estimated to accept an HIV test = 520 × 96% = 499.2 clients Round up to 500 clients
Monthly usage of first (screening) test	= Number of clients estimated to accept an HIV test per month plus monthly quality assurance requirements plus monthly wastage = 500 + (500 × 10%) + (500 × 10%) = 500 + 50 + 50 = 600 tests
Monthly usage of second (confirmatory) test	= Number of clients estimated to accept an HIV test per month plus monthly quality assurance requirements plus monthly wastage = 500 + (500 × 10%) + (500 × 10%) = 500 + 50 + 50 = 600 tests
Monthly usage of third (tiebreaker) test	= Number of clients estimated to accept an HIV test per month multiplied by discordance (%) To the answer add monthly quality assurance requirements plus monthly wastage = 500 × 2% = 10 + (10 × 100%) + (10 × 10%) = 10 + 10 + 1 = 21 tests

Calculation of Monthly Usage (U_m) Using the Morbidity Method and Service Statistics Data

This method uses information on service statistics (number of persons tested) and HIV prevalence to estimate monthly usage (Table A-4). The calculations for this method are very similar to those used for the morbidity method using demographic data.

Table A-4. Calculation of Monthly Usage with the Morbidity Method and Service Statistics Data

Step 1: Calculate the number of months that testing could be performed during the period being examined	= Add the number of days that testing could not be performed and divide by 30.5 Subtract the answer from the number of months during the period being examined
Step 2: Calculate the average number of clients tested per month	= Total number of clients tested for a given period divided by the number of months during the period that testing could be performed
Step 3: Make adjustments	Adjust the average number of clients tested per month for anticipated increases or decreases in demand

Serial Testing	Calculation of Monthly Usage (U_m)
Monthly usage of first (screening) test	= Average number of clients tested per month plus monthly quality assurance requirements plus monthly wastage
Monthly usage of second (confirmatory) test	= Number of first (screening) tests needed per month for specimen testing multiplied by HIV prevalence (%) To the answer add monthly quality assurance requirements plus monthly wastage
Monthly usage of third (tiebreaker) test	= Number of second (confirmatory) tests needed per month for specimen testing multiplied by discordance (%) To the answer add monthly quality assurance requirements plus monthly wastage

Parallel Testing	Calculation of Monthly Usage (U_m)
Monthly usage of first (screening) test	= Average number of clients tested per month plus monthly quality assurance requirements plus monthly wastage
Monthly usage of second (confirmatory) test	= Average number of clients tested per month plus monthly quality assurance requirements plus monthly wastage
Monthly usage of third (tiebreaker) test	= Average number of clients tested per month multiplied by discordance (%) To the answer add monthly quality assurance requirements plus monthly wastage

Example 2: Calculation of monthly usage (U_m) using the morbidity method and service statistics data

For an existing program, the following service statistics are available from the clinic register. For the period from April 2007 until March 2008, the clinic was unable to perform HIV testing for 54 days because it was out of stock of the first (screening) test and for an additional 10 days because of staff sickness.

Fiscal Year	Number of Persons Tested for HIV Per Month												Total	Total No. Persons Testing HIV Positive
	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar		
FY: 07/08	263	256	311	399	210	289	8	0	323	247	338	378	3022	405

Figure A-1. Service statistics

Requirements for quality assurance testing are estimated to be an additional 10 percent for the screening test, 10 percent for the confirmatory test, and 100 percent for the tiebreaker test. Wastage is estimated to be 10 percent for all three tests. Discordance is estimated to be 2 percent.

Steps to calculate average number of clients tested per month for the period from April 2007 until March 2008 are as follows—

1. Number of months in the period = 12
2. Number of days in the period that testing could not be performed = 54 + 10 = 64
3. Number of months in the period that testing could not be performed = 64 ÷ 30.5 = 2.1
4. Number of months in the period that testing could be performed = 12 – 2.1 = 9.9
5. Total number of clients tested from April 2007 to March 2008 = 3,022
6. Average number of clients tested per month = 3,022 ÷ 9.9 = 305.3, rounded up to 306

Steps to calculate HIV prevalence of clients tested at the clinic for the period from September 2007 until March 2008 are as follows—

1. Number of people tested in the period = 3,022
2. Number of persons testing HIV positive in the period = 405
3. Percentage of persons tested at the clinic testing HIV positive in the period = 13.4%

Table A-5. Example of Morbidity Method Calculations Using Service Statistics Data

Serial Testing	Calculation of Monthly Usage (U_m)
Monthly usage of first (screening) test	<p>= Average number of clients tested per month plus monthly quality assurance requirements plus monthly wastage = $306 + (306 \times 10\%) + (306 \times 10\%) = 306 + 30.6 + 30.6 = 367.2$ tests Round up to 368 tests (Note that 306 tests are needed for testing specimens and that this figure is used for calculating the monthly usage of the second [confirmatory] test below.)</p>
Monthly usage of second (confirmatory) test	<p>= Number of first (screening) tests needed per month for specimen testing multiplied by HIV prevalence (%) To the answer add monthly quality assurance requirements plus monthly wastage From above, 306 first (screening) tests are needed per month for specimen testing = $306 \times 13.4\% = 41.0 + (41.0 \times 10\%) + (41.0 \times 10\%) = 41.0 + 4.1 + 4.1 = 49.2$ Round up to 50 tests (Note that 41.0 tests are needed for testing specimens, and this figure rounded up is used for calculating the monthly usage of the third [tiebreaker] test below.)</p>
Monthly usage of third (tiebreaker) test	<p>= Number of second (confirmatory) tests needed per month for specimen testing multiplied by discordance (%) To the answer add monthly quality assurance requirements plus monthly wastage From above, 41 second (confirmatory) tests are needed per month for specimen testing = $41 \times 2\% = 0.82 + (0.82 \times 100\%) + (0.82 \times 10\%) = 0.82 + 0.82 + 0.08 = 1.72$ Because the number of tiebreaker tests used is so small, the requirements can be rounded up to whole numbers. One test can be allowed each month for discordance, one for quality assurance, and one for wastage, so estimated monthly usage (U_m) = 3 tests per month</p>
Parallel Testing	Calculation of Monthly Usage (U_m)
Monthly usage of first (screening) test	<p>= Average number of clients tested per month plus monthly quality assurance requirements plus monthly wastage = $306 + (306 \times 10\%) + (306 \times 10\%) = 306 + 30.6 + 30.6 = 367.2$ tests Round up to 368 tests</p>
Monthly usage of second (confirmatory) test	<p>= Average number of clients tested per month plus monthly quality assurance requirements plus monthly wastage = $306 + (306 \times 10\%) + (306 \times 10\%) = 306 + 30.6 + 30.6 = 367.2$ tests Round up to 368 tests</p>
Monthly usage of third (tiebreaker) test	<p>= Average number of clients tested per month multiplied by discordance (%) To the answer add monthly quality assurance requirements plus monthly wastage = $306 \times 2\% = 6.1 + (6.1 \times 100\%) + (6.1 \times 10\%) = 6.1 + 6.1 + 0.6 = 12.8$ tests Round up to 13 tests</p>

Calculation of Monthly Usage (U_m) with the Usage Method

This method uses inventory stock records to calculate monthly usage (Table A-6). The calculation is the same for parallel and serial testing and for all three types of tests.

Table A-6. Steps for Calculating Monthly Usage with the Usage Method

Step 1: Calculate number of months the product was in stock during the period being examined	= Add the number of days the product was out of stock and divide by 30.5 Subtract the answer from the number of months during the period being examined
Step 2: Calculate average monthly usage	= Total usage for a given period divided by the number of months during the period that the product was in stock
Step 3: Make adjustments	Adjust the monthly usage for anticipated increases or decreases in demand and for requirements for quality assurance or wastage

Example 3: Calculation of monthly usage (U_m) with usage method

For an existing program, the following information for the screening test is available from the inventory card. (Note that total usage does not include expired stock removed to be destroyed.) The test kit was out of stock for 54 days for the period from September 2007 until March 2008.

Fiscal Year	Monthly Usage												Total Usage	Expired
	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar		
FY: 07/08	-	-	-	-	-	300	100	0	400	700	700	900	3,100	200

Figure A-2. Sample inventory card

Steps to calculate average monthly usage for the period from September 2007 until March 2008 are as follows—

1. Number of months in the period = 7
2. Number of days in the period that product was out of stock = 54
3. Number of months in the period that product was out of stock = $54 \div 30.5 = 1.8$
4. Number of months in the period that product was in stock = $7 - 1.8 = 5.2$
5. Total usage from September to March (7 months) = 3,100
6. Average monthly usage = $3,100 \div 5.2 = 596.2$

In this example, however, average monthly usage for the past *four* months is 675 tests, and the monthly usage appears to be increasing. Therefore, the program manager decides to use 675 as the average monthly usage to calculate how much to order.

Calculation of Monthly Usage (U_m) with the Proxy Usage Method

This method uses monthly usage data from other points of service, regions, or countries and is extrapolated for specific situations on the basis of population coverage, prevalence, and requirements for quality assurance and wastage.

Example 4: Calculation of monthly usage (U_m) with the proxy usage method

A new mobile VCT program is starting in a remote region where prevalence of HIV is estimated from surveillance data to be 20 percent. The program will use the same testing algorithm as a mobile VCT program in another region where prevalence of HIV in clients who use the service is estimated from records to be 15 percent. Both programs will use serial testing, and levels of discordance are estimated to be similar at 1 percent. Demand for the new program is estimated to be initially half that of the existing program, which sees 300 clients per month for testing. Requirements for quality assurance will be similar, but wastage is estimated to be 20 percent, double that of the existing program level of 10 percent. The average monthly usage of the existing program is 360 screening tests, 56 confirmatory tests, and 2 tiebreaker tests per month.

Estimated monthly usage (U_m) of screening test is calculated as follows—

1. Existing program uses 360 tests per month and tests 300 patients
2. New program is estimated to have half the number of patients = $300 \div 2 = 150$
3. Additional quantity needed for 20% wastage (instead of 10%) = $150 \times (20\% - 10\%) = 150 \times 10\% = 15$ tests
4. New program is estimated to use $(360 \div 2) + 15$ tests per month = $180 + 15 = 195$ tests per month; round up to 200 tests per month
5. Estimated monthly usage (U_m) = 200 tests per month

Estimated monthly usage (U_m) of confirmatory test is as follows—

1. Existing program uses 56 tests per month
2. New program is estimated to have half the number of patients and so will use half the number of test kits = $56 \div 2 = 28$
3. Prevalence in the new program is 20% compared with 15% in the new program = $28 \times 20\% \div 15\% = 37.3$
4. Because the actual number of patients tested per month with the confirmatory kit is not known, needs for the additional wastage are estimated using the actual number of tests used (this will result in a slight overestimate)
Additional quantity needed for 20% wastage (instead of 10%) = $37.3 \times (20\% - 10\%) = 37.3 \times 10\% = 3.73$
5. New program is estimated to use = $37.3 + 3.73 = 41.03$ tests
6. Estimated monthly usage (U_m) = 42 tests per month

Estimated monthly usage (U_m) of tiebreaker test is as follows—

1. Existing program uses 2 tests per month
2. New program is estimated to have half the number of patients = $2 \div 2 = 1$

- Because the number of tiebreaker tests used is so small, the adjustments can be rounded up to whole numbers. One extra test can be allowed each month for the higher prevalence and one extra for wastage, so estimated monthly usage (U_m) = 3 tests per month

Calculating How Much to Order

When monthly usage for each type of HIV test kit has been estimated, it is time to order. The method used to calculate the quantity to order (Table A-7) is identical for all three types of HIV test kits, regardless of whether parallel or serial testing is used.

Table A-7. Calculating How Much to Order

Item	Abbreviation or Calculation	Explanation
Procurement period	PP	The period in months between orders. Because the expiration dates of HIV test kits are generally short, kits may need to be ordered more frequently than other supplies. New programs should order more frequently initially—for example, every two or three months—to avoid stock-outs or wastage caused by expiring stock.
Lead time	LT	Time between placing an order and the time the product is received and ready to use. For new programs, ask the supplier to submit an estimate of lead time or ask other programs that use the same supplier. Ongoing programs should estimate lead time from existing records.
Stock in inventory	S_i	Stock held in the facility that will not expire in the next procurement period. To calculate the quantity of HIV test kits at risk of passing the expiry date multiply the number of months until the kit expires by the average monthly usage (U_m) and subtract this figure from the stock in inventory (S_i). If the answer is negative, no stock should expire if current usage patterns continue. However, if the answer is positive, this is the amount of stock that is likely to expire if current usage patterns continue. Subtract this figure from the stock in the inventory and use the answer as S_i . In a new program, there will be no stock in inventory, so S_i will be zero.
Stock on order	S_o	Stock ordered but not yet received. (Back orders should be included here when there is a system in place to handle them.) In a new program, there will be no stock on order, so S_o will be zero.
Safety stock	$SS = U_m \times$ adjusted LT	Safety stock is stock on hand to protect against stock-outs. At a minimum, safety stock is the average monthly usage (U_m) multiplied by the lead time (LT). Each program must decide how many months of extra supply to keep. Existing programs should monitor usage and lead time and adjust safety stock to the lowest level compatible with current patterns to keep inventory costs down. Adding one or two months' supply to safety stock is one method of preparing for increased usage.
Maximum stock level (S_{max})	$S_{max} = SS +$ $(U_m \times PP)$	Multiply the average monthly usage (U_m) by the procurement period (PP) and add the safety stock (SS). Stock levels in a facility should not exceed this level.

Item	Abbreviation or Calculation	Explanation
Order quantity (in number of tests) (Q _O)	$Q_O = (S_{max}) - (S_I + S_O)$	<p>Add the stock in inventory (S_I) to the stock on order (S_O) and subtract this quantity from the maximum stock level (S_{max}). This is the quantity of tests that needs to be ordered.</p> <p>Divide this by the number of tests per kit to obtain the quantity of test kits to order.</p> <p>The number of tests per kit is different for each type or brand of test kit. For a new program, this information can be obtained from the manufacturer or supplier.</p>

Example 5: Calculation of quantity to order

An existing program has calculated that the average monthly usage (U_m) for the screening HIV test is 675. The procurement period (PP) is three months; lead time (LT) is one month; inventory stock (S_I) is 2,600 tests; stock on order (S_O) is 1,000 tests; and because the program is expanding, the program manager decides to add an additional month as safety stock (SS). The tests are packed as 100 tests per kit. Table A-8 shows the calculation process for this sample program.

Table A-8. Example of Calculations Used in Ordering

Item	Calculation	Calculation for This Example
Average monthly usage	U _m	675 tests
Procurement period	PP	3 months
Lead time	LT	1 month
Stock in inventory	S _I	2,600 tests (but 700 will expire before use at current usage rates, leaving 1,900 tests available for use)
Stock on order	S _O	1,000 tests
Safety stock	SS = U _m × adjusted LT	SS = 675 × (1 month + 1 month) = 675 × 2 SS = 1,350 tests
Maximum stock level (S _{max})	S _{max} = SS + (U _m × PP)	S _{max} = 1,350 + (675 × 3) = 1,350 + 2,025 = 3,375 tests
Order quantity (in number of tests) (Q _O)	Q _O = (S _{max}) – (S _I + S _O)	Q _O = 3,375 – (1,900 + 1,000) = 3,375 – 2,900 = 475 tests
Order quantity (in number of kits) (Q _O)	Quantity in number of tests divided by number of tests per kit	Q _O = 475 ÷ 100 = 4.75 kits Round up to 5 kits to order

ANNEX B: CHART TO TRACK THE EXPIRY DATES OF HIV TEST KITS

Standard Operating Procedure	
Expiry Date Monitoring of HIV Test Kits	
Number of pages: 2	Procedure number:
Prepared by: Name:	Reviewed by: Name:
Title:	Title:
Date:	Date:

Objective:

To describe the procedure for tracking the expiry dates of HIV test kits to alert supply/stock managers when HIV test kits should be removed from stock for exchange or destruction. Some suppliers will take back short-dated stock for exchange, but only if it is received with a certain minimum expiry—usually six months. Some programs may have arrangements to move short-dated stock to other points of service where consumption is higher. When test kits cannot be returned for exchange, the chart alerts staff to remove expired stock so that it does not get issued in error.

Responsibility:

- Staff member in charge of the storage area for HIV test kits

Resources:

Chart to Track the Expiry Dates of HIV Test Kits

- Is a laminated chart designed to hang on the wall.

Procedure:

1. The chart is designed to be reusable. Use a DRY pen to make entries. If you use a permanent marker, you will need to use spirit or other ink remover to make changes.
2. The chart has three columns for three years. The first column should be used for the current year.
3. At the beginning of each new year, shift the years on the column headings to delete the old year and add the next new year. The original second year now becomes the first year. Shift the stickers for the batches of HIV test kits that remain on the chart at the beginning of the new year to the new columns.
4. Each product has space to list five different batches/lots of each type of HIV test kit. If you have more than five batches/lots, record the five that expire first.
5. ● (yellow) marks the expiry warning date; ● (red) marks the month when the test kit expires.
6. Contact the product supplier to find out the minimum expiry date that the supplier will accept for exchange, or check with the program manager as to when he/she wants to be alerted about short-dated stock. Consider adding one month to this minimum date to allow for transport back to the supplier. Place the yellow warning dots on the month in which action must be taken.

7. For the three months before the yellow warning dot, enter the current stock level of that batch/lot in the relevant grid. The stock levels also show the rate of use and determine how much, if any, stock to return.
8. Remove the red dot only after the expired stock has been destroyed or removed from stock.
9. When a batch/lot expires or is used up, erase the entry and replace it with the next batch to expire. When a new supply of HIV test kits are received, enter the new batch/lot number and expiry date on the chart.

ANNEX C: EXAMPLES OF HIV COUNSELING AND TESTING COMMODITY REPORTING FORMS

Facility Monthly Test Kits and Other Supplies Inventory Report is a commodity reporting form designed for use at a stand-alone VCT center.

Facility Monthly Laboratory Test Reporting Format is a laboratory test reporting form designed for use at a site with multiple service delivery points.

Zambia VCT Service is acknowledged as the source of these forms.

Zambia VCT Service
Facility Monthly Test Kits and Other Supplies Inventory Report (FMIRP03.1)

Form: F5

(To be reported by each VCT/PMTCT laboratory to the DHMT [given to the **DHIO** for electronic data entry, and a copy sent to pharmacy] by the 7th of following month)

A: General Information		
Province : <i>The Province</i>	Month: <i>January</i>	Reported date: <i>2nd February</i>
District : <i>The District</i>	Year : <i>2008</i>	Report prepared by: <i>HP</i>
		Approved by: <i>MJ</i>

B: Stock of Kits		Use units for columns (a) to (z)										
Stock code or Lot no.	Name of commodity	Stock from last month	Received this month		Damaged this month	Expired this month	Used this month	Current Stock (a + b - c - d - e)	Average Monthly Consumption (Amc) ³⁷	Will last for (months) (w / AMC)	Will expire after (months)	Will actually last (months) - smaller number in (x) and (y)
	Pack size		From	Quantity								
(i)	(ii)	(a)	(b)	(c)	(d)	(e)	(w)	AMC	(x)	(y)	(z)	
100XDD700	<i>Determine</i> 1 = 100 tests	200	<i>District Pharmacy</i>	100	10	0	50	240	60	<i>4 Months</i>	<i>5 months</i>	<i>4 Months</i>
XX9DD	<i>Genie II</i> 1 = 40 tests	40	<i>District Pharmacy</i>	80	20	0	30	70	25	<i>2.8 Months</i>	<i>3 Months</i>	<i>2.8 Months</i>

C: Remarks and suggestions (Use this space to write your experience with respect to the supply, delivery and use of kits and other supplies along with relevant suggestions and recommendations. Some of the things that you might want to consider are the quality of kits and other supplies, storage space etc.)

³⁷ Add the quantity used during the last three months and divide by 3 to get Average Monthly Consumption (AMC). For example, if you are calculating AMC in March, add the consumption in December, January, and February, and divide by 3.

Zambia VCT Service
Facility Monthly Laboratory Test Reporting Format (FMLRP03.1)
(To be reported by each VCT/PMTCT laboratory to the DHMT by the 7th of following month)

Form: F6

A: General Information									
Name of Facility: <i>The Facility</i>							Reported date: <i>2nd February</i>		
Province: <i>The Province</i>			District: <i>The District</i>		Month: <i>January</i> Year: <i>2008</i>		Report prepared by: <i>KL</i>		
Approved by: <i>PKN</i>									

B: Number of Tests Conducted during the Month																					
Type of test <i>(Record each test instance)</i>	VCT				Clinic				Blood Bank				PMTCT				Other				Grand Total
	P	N	I	Total	P	N	I	Total	P	N	I	Total	P	N	I	Total	P	N	I	Total	
	<i>Test 1 (Abbot)</i>	21	66		87					17	88		105								
<i>Test 2 (Genie II)</i>	21			21																	21
<i>Test 3</i>																					
Total				108								105									213

C: Quality Control					
Number of samples sent to reference Centre Lab		<i>Nil</i>		Did you get feedback on the previous lot if any?	Yes No <i>Nil</i>
Number of samples received from UTH Lab				Did you get feedback on the previous lot if any?	Yes No

D: Remarks and Recommendations (Use this space to write your observations and experiences related to the testing of the samples. Also use this space to ask for support that you need to conduct the quality test.)

We are unable to take samples for quality assurance due to lack of logistic from the DHMT.



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Rational Pharmaceutical Management Plus
Center for Pharmaceutical Management
Management Sciences for Health
4301 North Fairfax Drive, Suite 400
Arlington, VA 22203-1627 USA