

# Managing Medicines and Supplies for HIV/AIDS Program Scale-Up

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**A**S COUNTRIES MOVE TO RAPIDLY scale up comprehensive HIV/AIDS programs, it is critical that the adequate and continuous availability of diagnostics, medicines, and other pharmaceuticals be ensured at the point of service. If HIV test kits are unavailable, opportunities to offer testing are missed. Stock-outs or irrational use of antiretroviral medicines (ARVs) can result in treatment interruptions that can quickly lead to treatment failure and the development of drug resistance. The success of these programs is also largely dependent on the capability of the health-care team to promote the proper use of ARVs and other products. Inappropriate use can increase the risk of toxicity of HIV/AIDS-related medicines and, in addition, can waste costly laboratory tests and medicines. Despite many improvements, the limited availability of ARVs and HIV test kits continues to be reported as a major constraint to scaling up programs.<sup>1-3</sup>

A wide range of medicines and other pharmaceutical products are needed to support implementation of a comprehensive package of HIV/AIDS services for treatment, care, and prevention (see Box 1). While a single health facility may not carry all needed products, clients should be able to

access products that are unavailable at their local facility through a referral process. Some services require new products, while others need large-scale increases in quantities of existing medicines and supplies. These requirements change as new technologies or formulations become available and as practices or patient needs change. In addition, some products are complex to manage, requiring cool or refrigerated storage and careful tracking of short shelf lives to minimize wastage.

## Box 1. Pharmaceuticals Needed to Support Comprehensive HIV/AIDS Programs

- Medicines:
  - Medicines to treat HIV infections (antiretrovirals)
  - Medicines to prevent and treat opportunistic infections (OIs)
  - Medicines for palliative and supportive care
  - Medicines to prevent and treat sexually transmitted infections (STIs)
  - Medicines to treat HIV-related cancers
- Diagnostic test kits for HIV, STIs, and OIs
- Laboratory reagents, supplies, and equipment:
  - To monitor the progression of HIV infection
  - To identify adverse drug reactions
- Medical equipment and supplies

The World Health Organization (WHO) estimates that at the end of 2006, only 28% of people in need of antiretroviral therapy (ART) in all low- and middle-income countries were receiving it and that steep increases in the rate of scale-up will be needed to achieve universal access to treatment by 2010.<sup>4</sup> As countries move to decentralize ART services to the primary health-care level, the pharmaceutical management system must meet the challenge of delivering supplies to more service delivery points, across different sectors, and for an increasing number of clients. In many countries, procurement and distribution systems are struggling to keep up with this rapid expansion, and even systems that are working well will be challenged to support the level of scale-up that is to come.<sup>4</sup>

This chapter provides practical guidance on addressing some of the major challenges related to the management of medicines and other supplies being faced by HIV/AIDS programs in resource-limited settings. Successful approaches and lessons learned for building the capacity of pharmacy and supply services to support scale-up are shared.

## APPROACHES TO STRENGTHENING SYSTEMS FOR GOING TO SCALE

As countries plan to scale up their HIV/AIDS programs, a key consideration is whether to integrate the supply of HIV/AIDS-related pharmaceuticals into an existing supply system or, alternatively, to establish one or more vertical or parallel systems. In a vertical supply system, all or some of the functions of the pharmaceutical management cycle (described below) are carried out separately for each program. Limitations to using parallel systems to supply HIV/AIDS programs include the wide range of products needed, the level of expansion to be achieved, and the shortage of skilled pharmaceutical management staff.

In many countries, governments are working with partners to rationalize multiple vertical

supply systems and to foster service integration. Most pharmaceutical management systems have some strengths to build upon. A rapid assessment can help clarify what these strengths are and help identify which strategies are needed to build capacity where it is lacking. By prioritizing interventions, facilities can begin implementing new HIV/AIDS programs while working to strengthen existing pharmaceutical management systems for the longer term. Integrating pharmacy and supply services into existing systems allows capacity-building costs to be shared across programs. Integration also ultimately improves pharmaceutical management for other programs, since most improvements are system-based rather than disease-specific. In addition, integrated systems are better equipped to support scale-up, due to the fact that service provision, such as ARV dispensing, does not depend on the availability of a specific member of the pharmacy staff.

## THE PHARMACEUTICAL MANAGEMENT SYSTEM

Managing pharmaceuticals in any setting (public or private) and at any level (local or national) follows a well-recognized framework that includes a cycle of *selection, procurement, distribution, and use* (see Figure 1). Management support functions hold the cycle together, and it is supported by policies, laws and regulations. As problems in any part of the cycle can disrupt the whole pharmaceutical management system, it is important that assessments of existing capacity consider all components of the framework.

### SELECTION

The successful scale-up of ART programs depends on good selection practices. Selection involves reviewing HIV-related health problems, developing standard guidelines, and deciding which medicines, diagnostics, and supplies will

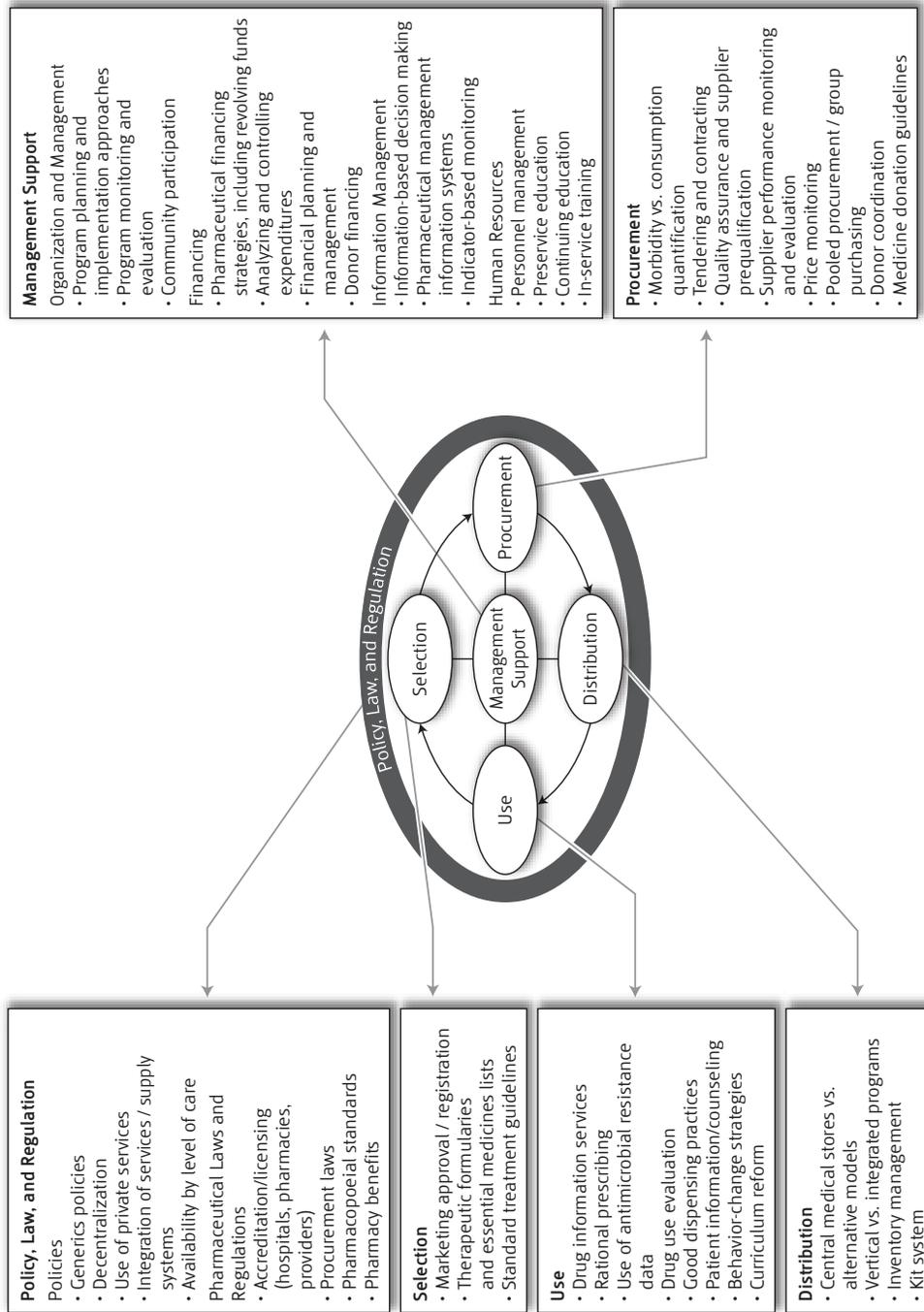


Figure 1. Pharmaceutical management framework

Source: Management Sciences for Health, 2007.

be available at each level of the health system. Good selection practices include the rational selection of the most effective and economical treatments or tests for a specific setting, performed through an inclusive and transparent process and underpinned by a plan for implementation. The benefits of standardization for selected testing and treatment protocols include more predictable demand for products, which allows for more accurate quantification; fewer products to procure and store; and lower prices due to bulk purchasing. However, ART selection is complicated by the need for multiple regimens to cover different indications and populations. Lack of clarity about regimen choices and multiple formulation options can confuse prescribers and complicate quantification. Rapidly changing scientific information on effectiveness, adverse effects, or resistance patterns, and the availability of new medicines or formulations, makes it difficult to keep ART guidelines current. However, if guidelines are perceived to be outdated or not based on scientific evidence, prescribers are less likely to follow them.

## Points to Remember for a Successful Approach

**Comprehensive and detailed guidelines help standardize practices and improve quantification accuracy.** Although most countries have developed national guidelines for their HIV/AIDS interventions, program and procurement staff can encounter difficulties in implementing these recommendations. This is particularly true when the clients are children. Programs are better able to quantify needs and standardize procedures for prescribing and dispensing when ART guidelines specify the following:

- First- and second-line regimens, with recommendations for managing toxicity and treatment failure

- Regimens for individuals coinfecting with TB and other chronic diseases, as well as for pregnant women and all age groups of children
- Regimens for postexposure prophylaxis (PEP) in both adults and children
- Guidance on managing the ART-experienced patient
- Recommendations for laboratory monitoring
- Recommendations for diagnosis and treatment of opportunistic infections (OIs) for both adults and children
- For children, a range of products to suit all ages, preferred formulations for weight and age, and weight-based dosing recommendations for available products (WHO has developed generic dosing tables for countries to adapt for this purpose.<sup>5</sup>)

**An inclusive and transparent development process facilitates implementation of and adherence to guidelines.** The inclusion of service providers and national pharmaceutical management staff in selection committees enables them to contribute to developing guidelines that are easier to put into practice. In addition, participation by representatives of the essential medicines committee can facilitate the addition of products to the lists that guide procurement. Including a wider range of constituencies (organizations or groups) can, in general, help build the credibility and acceptance of guidelines.

**Updating guidelines requires planning and adequate budgeting.** Regular updates to HIV/AIDS guidelines are necessary but can be costly. The process of planning and securing adequate funding in advance of any changes is very important. For instance, training materials, standard operating procedures (SOPs), supply management forms, and reporting and recording forms may all need to be updated. The launch of the new guidelines also needs to be synchronized with supply management, as it takes time to quantify, procure, and

distribute new products and to use up existing products already in the supply pipeline. Communication is a critical component of this process.

In addition, organizations and donors that provide support to HIV/AIDS programs (particularly those that procure pharmaceuticals) need to be informed of proposed changes early on to enable them to prepare for and support implementation. New guidelines need to be printed and copies disseminated to all facilities and staff providing services in the public and private sectors ahead of the implementation of new recommendations to avoid problems resulting from confusion or lack of coordination.

## PROCUREMENT

Pharmaceutical procurement consists of quantifying product needs, selecting procurement methods and suppliers, establishing and monitoring contract terms, and ensuring the quality of the medicines and other pharmaceuticals. Quality should never be compromised by pricing concerns or any other factor. In many countries, the complexity of procuring products for HIV/AIDS programs is challenging already weak procurement systems. The increased number of global and local partners, funding sources, and procurement mechanisms has complicated procurement planning, occasionally resulting in duplicative procurements and stock-outs. These complications are compounded by the fact that different funding sources can have different procurement cycles and requirements, resulting in complex record keeping, more orders to generate and track, and multiple brands of the same product.

Quantifying needs for ART programs that are scaling up is particularly challenging. The pace of program expansion often fluctuates over time, and enrollment may periodically slow down when the capacity to deliver services has reached its limit.<sup>6</sup> Staff tasked with quantifying needs at the national level are often handicapped by the lack of reliable

data from facilities. Changing needs for ARV regimens as patients experience toxicity or treatment failure can also be hard to forecast. Similarly, estimating requirements for new medicines as guidelines change or new formulations, such as fixed-dose combinations (FDCs), become available can be complex. Further complicating the process are lengthy procurement procedures and long supply pipelines that can delay the introduction of new products.

### Points to Remember for a Successful Approach

**A national committee to coordinate procurement and distribution can optimize the purchasing power of multiple partners and improve the efficiency of pharmaceutical management.** To improve the coordination of procurement, financing, and distribution activities, some governments have established national-level committees to support HIV/AIDS program expansion. The committee serves as a forum for planning collaborative action to strengthen the pharmaceutical management system. Although procurement managers are responsible for most activities, the committee enables them to work together with policy and program staff to map out current and anticipated service delivery points and targets. This collaborative process should lead to the development of a comprehensive procurement and distribution plan that includes an accurate estimate of resource needs. The committee can also work with the team tasked with quantification to review the quality of data collected and develop assumptions about future needs. It is also crucial that the procurement and distribution plan be updated regularly to ensure that procurement planning, program implementation, and disbursements of funds are synchronized.

**Simple tools and training can improve quantification and data collection at the facility level.** The provision of simple tools to assist facility-level

## CASE STUDY 1: THE COORDINATED PROCUREMENT AND DISTRIBUTION SYSTEM FOR ANTIRETROVIRALS IN RWANDA

**T**HE GOVERNMENT OF RWANDA has established the Coordinated Procurement and Distribution System (CPDS) to coordinate ARV procurement and distribution efforts among the government, donors, national institutions, and international organizations. The President's Emergency Plan for AIDS Relief (PEPFAR), through the U.S. Agency for International Development (USAID), committed funds to the Rational Pharmaceutical Management Plus (RPM Plus) Program to support this coordination process. The CPDS had its beginnings in 2005, when the government coordinated the first national quantification and pooled procurement of ARVs. In 2006, a governance framework that describes CPDS objectives and functioning principles and the roles of its members, developed by consensus with all national and international stakeholders, was approved by the Ministry of Health. The CPDS has two primary components:

- A Resource Management Committee, chaired by the permanent secretary of the Ministry of Health and responsible for political, strategic, and financing decisions
- Technical committees responsible for procurement, quantification, distribution, and monitoring functions

The two components are linked by a coordinator who provides technical advice to the permanent secretary and coordinates the technical committees.

The coordination activities of the CPDS have simplified ART management and lowered costs by harmonizing formulations and brands, reducing wastage, and decreasing the number of purchase orders.<sup>7</sup> Furthermore, to support its coordination efforts, the CPDS has accelerated efforts to strengthen the pharmaceutical sector. Pharmaceutical procedures and tools have been standardized, and pharmacy staff have been trained in pharmaceutical management.

*Source:* Adapted from Tarrafeta B. *The Coordinated Procurement and Distribution System in Rwanda: Empowering Local Systems beyond Supplying ARVs*. Arlington, VA: Management Sciences for Health; 2007.

staff in data collection and quantification of ARV and other product needs, coupled with training to improve staff quantification skills, can reduce stock-outs and the need for emergency orders. For district and frontline facilities that are scaling up ART, a modified consumption-based method of quantification is simpler to use than a morbidity-based method. From initial experiences, the consumption-based method appears to be sufficiently accurate, provided that consumption records are

reliable, procurement periods do not exceed three months, and the pipeline is full.<sup>8</sup> Data collection tools developed in collaboration with facility staff who actually use the data to quantify needs can improve the quality of the data collected and subsequently submitted to the national level.

**Contracts should allow procurement to be flexible and responsive to fluctuations in scaling up.** Procurement contracts should include staggered deliveries and allow adjustments to be made

to order quantities in case scale-up goes faster or slower than expected.

## DISTRIBUTION

Distribution includes clearing customs, stock control, storage management, and delivery to depots and service delivery points. The drive to scale up access to HIV/AIDS programs is exposing weaknesses in the distribution systems of many resource-limited countries. Public-sector supply systems, especially in African countries, are struggling to manage hugely increased volumes of medicines, diagnostics, and other pharmaceuticals. Faith-based and other nongovernmental organizations (NGOs) that supply their own facilities are unlikely, even with expanded capacities, to be able to fill the gap as countries take their programs to scale.<sup>9</sup> Multiple funding streams and parallel procurement systems result in multiple shipments needing to be cleared through customs. In most countries, this is a complex and time-consuming process.

The high value and short shelf life of some HIV/AIDS pharmaceuticals, coupled with frequently changing guidelines and the ongoing introduction of new formulations and technologies, puts pressure on supply managers to keep pipeline stock to a minimum while avoiding stock-outs. This is especially true for ARVs. Because scale-up is unpredictable and patients' needs can change, interventions such as ART require frequent deliveries to a constantly increasing number of service delivery points.

### Points to Remember for a Successful Approach

**Multifaceted strategies and long-term investments are needed to build the capacity of supply systems for going to scale.** Countries are exploring a number of options to strengthen national distribution systems in order to support rapid

scale-up, including collaboration with faith-based NGOs and the harnessing of resources within the private sector. Some programs use a combination of distribution mechanisms to increase responsiveness. For example, they may use existing public-sector transport for routine orders and lease private vehicles or use express mail for emergency orders. Additional investments may be needed to improve the security, capacity, and integrity of storage sites at all levels, and to lease or purchase vehicles.

Strengthening inventory management will require resources for training as well as tools to help track commodities and monitor usage at central and site levels. Additional human resource needs may include an individual to coordinate distribution at the national level, and staff time for data collection and supervision. Where systems are integrated, efforts and resources expended to support HIV/AIDS program scale-up can strengthen the supply and distribution of all essential medicines.

**Introducing flexibilities to make distribution systems more responsive can help avoid stock-outs, minimize wastage, and facilitate the introduction of new products and formulations.** Strategies that can make distribution systems more flexible and responsive to users include increasing the frequency of deliveries, collecting and redistributing excess or short-dated stock, and processing nonroutine orders in a timely manner. Organizing the distribution system so as to limit the number of levels where stock is held can serve to minimize pipeline stock. Such an approach will vary depending on the local context. Some countries have centralized storage at the national level and use a relay system to move supplies to regional and district levels, while others, especially geographically large countries, have decentralized storage to one or more levels in the health-care system. In order to work well, a central management unit should be responsible for coordinating

## CASE STUDY 2: STRENGTHENING DISTRIBUTION SYSTEMS TO IMPROVE GEOGRAPHICAL ACCESS TO ANTIRETROVIRALS IN ETHIOPIA

**A**S ETHIOPIA ROLLS OUT ART services, the challenges for distribution include the vast size of the country, the lack of all-weather roads to some facilities, ambient temperatures in certain regions that frequently exceed 30 degrees Celsius, and inadequate storage infrastructure at new sites. To deliver quality ARVs when and where they are needed, the Ministry of Health's Pharmaceutical Supply and Logistics Department (PSLD) is working closely with PHARMID (the partly government-owned pharmaceutical company) and partners funded by PEPFAR, including the RPM Plus Program, to ensure that efforts are well coordinated. The distribution system for ARVs purchased with grants from the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) has been integrated with the system

used for PEPFAR-funded ARVs to increase efficiency. A distribution plan is developed quarterly; allocations are based on national "road map" targets and adjusted for uptake figures reported by sites. To minimize pipeline stock, ARV medicines are relayed out to PHARMID regional stores and directly on to facilities, which keep just one month of buffer stock. Regional pharmacy staff assist with responding to nonroutine orders and redistributing excess stock. A combination of transport mechanisms, including air, land, and courier services, is used according to the geographical context and the urgency of the order. Facility storage areas are being renovated and staff are being trained on the importance of proper storage of ARVs, including routine temperature monitoring of storage areas.

*Source: Management Sciences for Health / RPM Plus Ethiopia office.*

distribution, communicating with facility staff and program managers to update distribution plans and reallocate supplies based on uptake, and maintaining a robust information system that feeds data on consumption or requirements back to the central unit.

**At new sites, allocating "ceilings" for new ART patients can facilitate distribution planning.** Allocating monthly targets or ceilings for new patients can assist with distribution planning,<sup>10</sup> especially in the early phases of scale-up, when facilities lack data and experience to calculate requirements accurately.

## USE OF PHARMACEUTICALS

The availability of pharmaceuticals alone does not ensure access to quality care. Medicines must be properly prescribed and dispensed and clients must use them correctly. For the patient, irrational prescribing and dispensing and poor adherence to ARVs and other anti-infectives can lead to treatment failure and the development of drug resistance. Pharmacy staff play a key role in promoting rational use, and the importance of dispensing activities is frequently underestimated. Very often, pharmacies are understaffed, labels and appropriate packaging are unavailable, and staff lack

the basic skills and access to current information necessary to properly counsel patients and advise prescribers.

ART adherence has received much attention, and many clinics and pharmacies collect substantial amounts of data. However, validated measurement tools for monitoring adherence in resource-limited settings are few,<sup>11</sup> definitions of adherence and defaulting vary, and approaches to improving adherence are not always consistent.<sup>12</sup> Dispensing medicines for children presents a set of additional challenges. For instance, calculating doses can be complex. Formulations that require the cutting of tablets or the accurate measurement of three different medicines make the delivery of counseling messages to the caregivers of young patients more complex.

### Points to Remember for a Successful Approach

**Pharmacy staff can play a key role in promoting and monitoring ART adherence.** Studies in the developed world have found that support from pharmacists can positively affect adherence<sup>13</sup> and that clinical pharmacists appear to have a strong impact on promoting positive clinical outcomes in patients starting ART, particularly in economically disadvantaged areas.<sup>14</sup> In resource-limited settings, the contributions of traditional pharmacy activities (e.g., checking prescriptions, labeling medicines, and providing medication counseling) in facilitating ART adherence are increasingly being recognized. These responsibilities are also expanding to include adherence monitoring and identification of defaulting patients.

As programs scale up, it becomes more challenging to maintain the quality of pharmaceutical care. Resources can be stretched thin as patient numbers increase and ART dispensing is decentralized to facilities that lack trained pharmacy staff. Delineating health-provider roles in

adherence counseling to eliminate unnecessary duplication of efforts can increase efficiency at the pharmacy. Furthermore, validated methods to monitor adherence can enable pharmacy staff to target interventions appropriately. Appropriately adapted SOPs that detail dispensing, adherence counseling, and monitoring processes, and job aids such as medication counseling checklists, can help maintain the quality of pharmacy practices. User-friendly information on ARV medicines, side effects, and interactions can also assist pharmacy staff in communicating key messages to their patients.

**Special efforts should be made to enable pharmacy staff to support ART rollout for children.** Pharmacy staff play an important role in checking ART prescriptions and doses for children, and in providing counseling to their caregivers. When information is lacking or nurse counselors are unavailable, health providers often rely on pharmacy staff to fill the gap. In addition to training in pediatric ART, pharmacy staff may also need to improve their math skills to be able to correctly calculate doses of medicines and quantities to dispense. Information on regimens and dosing recommendations, as well as advice for caregivers on special challenges, should be readily available. In addition, dispensing supplies such as labels, tablet cutters, and measuring devices should be provided. Colored tape can be helpful to distinguish similar-looking bottles of liquid formulations.

**Strengthening dispensing and medication counseling practices for ART programs can improve pharmaceutical care for all patients.** Where ART dispensing is integrated into existing systems and work schedules, staff can often adapt their training in ART medication counseling to improve the quality of counseling for other programs, particularly for patients on chronic treatments, such as for hypertension or diabetes.<sup>15</sup>

## CASE STUDY 3: DEVELOPING A TOOL FOR MONITORING ANTIRETROVIRAL THERAPY ADHERENCE IN SOUTH AFRICAN CLINICS

IN SOUTH AFRICA, THE RPM PLUS Program, with funding from USAID, is assisting the national and provincial (Eastern Cape) HIV and AIDS directorates and partners to identify a simple, nonelectronic medication adherence assessment tool that can be used by pharmacy staff and other providers at busy ART clinics. An initial literature search revealed that numerous instruments were available; however, no studies described their routine use in resource-limited settings. Given that a 2003 WHO report<sup>16</sup> concluded that no gold standard for measuring adherence existed and recommended a multi-method approach, RPM Plus developed a multimethod adherence assessment tool based on

previously validated tools, namely, self-report, visual analogue scale, pill identification test, and pill count. The tool was tested at two hospital pharmacies over a 14-month period. The median time of five minutes to administer the tool was deemed acceptable for routine use, and the internal consistency was sufficiently strong to recommend piloting the tool in all provinces. In May 2007, the Comprehensive HIV and AIDS Care, Management and Treatment Plan National-Provincial Working Group agreed to implement the adherence assessment tool in all provinces, and RPM Plus was requested to develop a similar tool for use with children. The intent is to then adapt these tools for other chronic diseases.

*Source:* Steel GS, Banoo S, Paterson M, et al. Development of a multi-method medication adherence assessment tool suitable for antiretroviral therapy facilities in resource-constrained settings. Paper presented at: 134th American Public Health Association Annual Meeting and Exposition; November 4-8, 2006; Washington, DC. Abstract 139069.

## POLICIES, LAWS, AND REGULATIONS

The pharmaceutical management framework includes all policies, laws, and regulations that impact the availability and use of medicines and other pharmaceuticals. This discussion focuses on one aspect of this framework, pharmaceutical registration. Pharmaceutical registration is the licensing or market authorization of a product based on evidence of efficacy, safety, and quality. The requirements and processes for registering products vary from country to country but will usually involve submission of a scientific dossier and, in some instances, a site visit. In developing countries,

the registration process for new products can be lengthy, in some cases taking a year or longer, which can impede the introduction of new HIV/AIDS-related medicines or formulations, such as FDCs for children. The time taken to review dossiers and conduct site visits and the submission of incomplete dossiers by manufacturers may all contribute to these delays.

### Points to Remember for a Successful Approach

**Fast-track registration and recognition of efficacy and safety evaluations by another medicine regulatory authority can facilitate the introduction**

**of new products for HIV/AIDS programs.** Establishing a fast-track mechanism that prioritizes the evaluation and processing of registration applications for specific categories of pharmaceuticals, such as ARVs, is one strategy to expedite registration. Some countries recognize the efficacy and safety evaluations of other medicine regulatory authorities (e.g., countries participating in the International Conference on Harmonization [ICH]) to accelerate the registration process. Strategies to capacitate the regulatory authority to conduct dossier evaluations and manage the workload may include establishing a medicine registration database, staff training, implementing SOPs, and developing a database to manage the dossier review process.

**As registration can be one of the longest and most difficult steps in updating guidelines, program managers should begin working with manufacturers early on to initiate the process of registering products.**

## MANAGEMENT SUPPORT: FINANCING

Funding for HIV/AIDS programs has increased significantly through large-scale initiatives such as the Global Fund, PEPFAR, and other donor initiatives. For many developing countries, achieving the exponential increases needed to take their programs to scale will depend on their success in securing external sources of funding. This funding is crucial not only for procurement, but also for the establishment of efficient pharmaceutical management systems that will function for years to come. The process for developing proposals, costing requirements, and gathering supporting information can be complex; delays in disbursement of Global Fund grants are common and may arise due to difficulties in developing procurement and supply management (PSM) plans, or in getting them

approved. As discussed earlier, the large number of pharmaceuticals needed for comprehensive HIV/AIDS programming may require joint planning and budgeting between partners and different government departments.

## Points to Remember for a Successful Approach

**Developing a multiyear financing strategy as part of an overall HIV/AIDS plan and establishing a mechanism to coordinate proposal development and donor inputs facilitates resource planning.**<sup>17</sup>

Programs should prepare multiyear forecasts of medicine needs to inform resource mobilization efforts. These forecasts should incorporate product procurement fees and shipping and importing costs into the budget. Financial resources for building the capacity of the pharmaceutical management system at both the facility and national level, including costs for technical assistance, should also be considered. Joint planning and budgeting with other government departments and programs can maximize efficiency in procurement and capacity-building activities. Moreover, donors may be more willing to invest in system strengthening if they know that activities will be cofunded from other sources.

**Begin the process of developing PSM plans early to avoid delays in disbursement of Global Fund grants.** Difficulties are most often encountered during the collection and verification of data to support the PSM plan, the forecasting of needs, and the development and budgeting of strategies to strengthen pharmaceutical management systems. Requests for technical assistance to help prepare the plan can take time to process. Having a mechanism in place to coordinate procurement, particularly quantification, and capacity-building efforts can facilitate the development of the PSM plan.

## MANAGEMENT SUPPORT: PHARMACEUTICAL MANAGEMENT INFORMATION SYSTEMS

An effective pharmaceutical management information system (PMIS) collects, analyzes, and reports information for program monitoring and decision making. For comprehensive HIV/AIDS programs that are scaling up, a well-functioning PMIS is essential to maintain the availability of ARVs and other pharmaceuticals and to monitor appropriate use, including adherence. To support the flexible and responsive supply functions discussed earlier, managers need a dynamic and accurate system to inform procurement and distribution planning, and particularly to alert them to potential stock-outs or surpluses.

Reliable data are needed to forecast and budget needs for pharmaceuticals, and also to estimate additional staffing and storage requirements for going to scale. Improving accountability and creating an audit trail to track products that enter and leave the supply system are also important functions of a PMIS. Managers will usually need this data to account for pharmaceutical expenditures to governments and donors. Although much is expected of the PMIS, existing systems in many developing countries are weak and struggle to meet the challenge of collecting and handling data from an increasing number of service delivery points and for a wider range of products.

### Points to Remember for a Successful Approach

**A long-term strategy and investment to establish a well-functioning PMIS is essential to support HIV/AIDS programs as they scale up.** Efforts to strengthen PMIS systems can take time but ultimately can improve the effectiveness of all pharmaceutical management functions. These benefits can extend to the management of other essential medicines in cases where programs are integrated.

Furthermore, a well-functioning PMIS can help managers secure resources for scaling up their programs (see Case Study 4). Building on existing forms, reports, and procedures helps keep costs down and can facilitate acceptance by users. Where multiple supply systems exist with separate information systems, countries will need a strategy for working with stakeholders to standardize data collection tools and reporting requirements to facilitate integration. Improvements to the PMIS are often incremental; transitions are made from manual systems to interim computerized tools to complete software systems as tools become available and patient numbers grow. Changes are made at each step to support new responsibilities or to overcome emerging challenges as programs scale up. Ongoing funding will be needed to develop and maintain the PMIS, and budgets should include costs for printing forms, updating tools, and training, as well as staff time to collect, report, and monitor data quality.

**Pharmacy staff need tools, including simple software, to help them collect, analyze, and report data.** The data complexity, especially for pediatric ART, the growing number of patients, and the wide range of products can make manual methods of maintaining records and retrieving data more and more difficult to use. As programs outgrow manual tools and pharmacy staff expand pharmaceutical care activities (e.g., adherence monitoring), managers may need to plan and budget for the implementation of user-friendly computerized tools to facilitate record keeping and analysis. Similarly, procurement and distribution staff will need tools to track HIV/AIDS pharmaceuticals by program and funding source as they move through the supply chain. Accuracy in data collection is always a paramount consideration, and poor data-collection practices may not necessarily be improved by computerization. It is important to computerize at appropriate levels to achieve the right mix of

## CASE STUDY 4: STRENGTHENING THE PHARMACEUTICAL MANAGEMENT INFORMATION SYSTEM IN SWAZILAND TO SECURE GLOBAL FUND ALLOCATIONS FOR ANTIRETROVIRALS

**T**HE FIRST IN-COUNTRY ASSESSMENT by the Global Fund required Swaziland to implement a reliable patient-monitoring and ARV-tracking system before the Global Fund would authorize funds of about US\$7 million to purchase ARVs to support expansion of the national HIV/AIDS program. In January 2006, the Ministry of Health and Social Welfare, with assistance from the RPM Plus Program funded by USAID, began strengthening ARV supply management systems at all levels in the country by installing an integrated, computerized pharmaceutical management software—RxSolution—that supports the management of orders, receipts, issues, stocks, and dispensing of medicines at ART facilities.

*Source:* Sallet J-P, Fakudze F, Ntengu M, Sibiyi T, Sigl E. Securing Global Fund allocation by strengthening supply management systems in Swaziland. Paper presented at: 3rd South African AIDS Conference; June 5-8, 2007; Durban, South Africa. Abstract 881.

By the end of July 2006, 11 hospitals and health centers were using RxSolution, and the ordering, inventory management, distribution, and dispensing of ARVs was fully computerized. In addition, system users were generating routine management reports to monitor stock levels and consumption trends, patient loads, and prescribing practices, and submitting them to national- and facility-level managers. By February 2007, no ARV stock-outs had been reported, and in May 2007, the local funding agent recommended that the funding restriction be lifted and that the patient monitoring system be integrated into RxSolution.

computer and manual systems and to provide the necessary training and support.

### MANAGEMENT SUPPORT: MONITORING AND EVALUATION

Monitoring and evaluation provide the integral link between planning for scale-up and implementation. The challenge for many countries lies in sustaining the quality of pharmacy services as operations expand. With this expansion, managers need to monitor the performance of the pharmaceutical management system without overburdening staff

with reporting requirements. Operations research can help identify important lessons on how best to strengthen pharmacy systems for scaling up HIV/AIDS interventions in a way that improves services for all health-care programs.<sup>18</sup> Most importantly, programs are often required to demonstrate results to support new proposals or justify requests for ongoing funding. Pharmacovigilance systems for monitoring adverse events for newly introduced medicines such as ARVs, and for monitoring the quality of products in the marketplace, are commonly weak in developing countries.

## Points to Remember for a Successful Approach

**Regularly monitoring a few key pharmaceutical management indicators can help managers detect problems early and address them promptly.**

Pharmacy managers at both central and facility levels should identify a small set of well-defined indicators and ensure that the PMIS routinely collects data to generate and report these indicators. Indicators are useful for evaluating the impact of an intervention designed to address a pharmaceutical management problem and are essential for demonstrating results to donors.

**Existing mechanisms for monitoring and evaluation should be used where possible.** To minimize the monitoring workload, checklists used for self-monitoring by the pharmacy staff or by supervisors can be adapted to add selected HIV/AIDS program parameters. Similarly, selected HIV/AIDS medicines can be included in the tracer medicine list used by supervisors to track the performance of the essential medicine supply systems. Integrated monitoring systems also enable managers to promptly identify negative effects of HIV/AIDS scale-up on other programs. Efforts to strengthen pharmacovigilance and quality surveillance for HIV/AIDS medicines can be an opportunity to strengthen or develop national systems where none exist.<sup>19</sup>

## MANAGEMENT SUPPORT: ORGANIZING SYSTEMS AND SUPPORTING PHARMACY STAFF FOR GOING TO SCALE

The benefits of establishing mechanisms at the central level to coordinate procurement and capacity-building activities have been discussed. Likewise, good communication and coordination at the facility level are essential for successful supply management in order to support program introduction and scale-up. Technical and programmatic

pharmaceutical management issues will need to be addressed as operations expand. Likewise, the pharmacy will need to set up linkages with other service providers to deliver services effectively, for example, to manage referrals to other departments within the facility or to follow up with patients who are late in collecting their ARV medicines.

The availability of HIV/AIDS-related medicines is dependent upon the leadership, planning, and management capabilities of pharmacy staff as well as their ability to forecast, order, distribute, and monitor pharmaceuticals effectively. However, pharmacists are in short supply in many developing countries, especially in the public sector and rural areas.<sup>20</sup> Other staff must learn new skills and take on new roles where severe shortages of pharmacists exist so that pharmacists can focus on essential oversight activities. Training and retaining pharmacy workers as programs expand to include new interventions and practices is vital for the long-term success of HIV/AIDS initiatives. Training approaches that use one-time intensive sessions to transfer large amounts of information rarely lead to lasting improvements in practice and are even less useful where staff turnover is high.

## Points to Remember for a Successful Approach

**A facility-level committee, such as an ART team, that plans and reviews progress in scale-up can anticipate pharmaceutical management constraints and address problems promptly as they emerge.** The ART team can also help the pharmacy staff quantify needs by identifying potential changes in guidelines or prescribing practices and developing projections for expansion. The role of the various staff in providing medication counseling can also be reviewed to identify gaps in the information being provided to patients and unnecessary duplication of efforts.

## CASE STUDY 5: TRANSITIONING THE MANAGEMENT OF ANTIRETROVIRALS AND RELATED PHARMACEUTICALS IN LAOS

**T**HE LAO PEOPLE'S DEMOCRATIC Republic has been providing services for the diagnosis, care, and treatment of people living with HIV since 2001, with the financial and technical support of Médecins Sans Frontières (MSF). As of September 2007, 663 patients, including 44 children, were receiving ARVs in two outpatient sites.

MSF will continue its support through September 2008, when the Lao Ministry of Health (MOH) will take over responsibility for managing the ART program through the Center for HIV/AIDS/STI, which has to date primarily provided policy and technical guidance. Support for the ART program will be provided through Round 6 funding from the Global Fund.

This transition requires careful planning, since the MOH has not been responsible for the process of quantification, procurement,

importation, and distribution of ARVs and other pharmaceuticals, nor the overall management of the program. Furthermore, the provision of medicines in Laos is fragmented, and essential programs are largely donor driven. MSF has implemented manual and electronic systems to track data for patient care and the management of medicines, and supported personnel dedicated to data entry and monitoring and supervision. The MOH plans to expand ART access to five sites within two years, and for three of these sites, implementation of ART will be a new undertaking. MSF has begun planning this transition together with the MOH. It is anticipated that this will be a collaborative process with partners to develop a comprehensive transition plan, evaluate technical assistance needs to support its implementation, and identify human and other resources needed.

*Source:* Médecins Sans Frontières Switzerland / Laos office and Management Sciences for Health / RPM Plus.

### **The pharmacy may need to establish linkages for a variety of tasks:**

- Managing referrals to and from other facilities
- Following up on patients who are late in collecting ARVs
- Reporting adverse drug reactions
- Providing pharmaceutical support to sites without a pharmacist
- Informing patients about other services at the facility or in the community

**Partnerships can enable governments to quickly fill priority vacancies in the public pharmaceutical sector and gradually absorb new**

**personnel.** By basing human resource interventions on existing government systems, donors and technical assistance partners can facilitate their eventual integration. In Namibia, PEPFAR committed funds through USAID to support additional pharmacy positions. The Management Sciences RPM Plus Program worked with the Ministry of Health and Social Services to develop a mechanism to hire pharmacists and assistants for priority positions. These positions were aligned with ministry priorities, job descriptions were made commensurate with the public sector, remunerations were set in accordance with government policies, and

ministry staff were involved in selection and supervision. After two years, 18 of 28 pharmacy staff recruited by RPM Plus to support ART scale-up had been absorbed into the government system.<sup>21</sup>

**Pharmacists need training, tools, and a supervisory structure in order to be able to provide technical oversight to facilities without a pharmacist.** Pharmacists need good leadership, management, and communication skills to mentor and assist staff to resolve problems and improve services. Support can include assisting staff to quantify needs and calculate storage requirements for program scale-up, implementing SOPs, and assisting teams in conducting rational-medicine-use reviews.

**To achieve capacity-building goals for pharmaceutical management, countries need a national training strategy that synchronizes needs for trained pharmacy staff with scale-up goals and incorporates strategies to prepare health-care staff to take on new roles.** Performance improvement strategies, such as the monitoring, training, and planning (MTP) approach,<sup>22</sup> that empower pharmacy staff to achieve and sustain improvements in the workplace can be an effective alternative to traditional training approaches.

## **MANAGING REAGENTS, SUPPLIES, AND EQUIPMENT FOR THE LABORATORY: SPECIAL CONSIDERATIONS**

In this section, some of the issues that are specific to managing laboratory reagents, supplies, and equipment for HIV/AIDS programs are briefly discussed. Other chapters in this section discuss laboratory diagnostics and patient monitoring at greater length. Interventions to strengthen supply management at the laboratory are usually developed as part of a national laboratory strategy by the ministry of health and national public health laboratory in collaboration with partners, such as the Centers for Disease Control and Prevention

(CDC). To be effective, efforts to improve the availability and management of laboratory commodities must complement and support the efforts and inputs of the CDC and other partners who work with governments to build laboratory capacity in developing countries and provide assistance in obtaining equipment, reagents, and other critical supplies. A lack of functioning equipment and interruptions in the supply of laboratory reagents are common to HIV/AIDS programs in many developing countries. Laboratory commodity management systems are invariably weak due to years of underinvestment and neglect. Although funding for reagents, equipment, and supplies has increased substantially in some countries in recent years, laboratory management systems in general will require substantial strengthening in order to leverage and absorb these additional investments. The lack of standardization of laboratory supplies and equipment makes procurement and quantification difficult, and many countries do not yet have a dedicated budget for laboratories. Many laboratory tests are used for other programs in addition to HIV/AIDS, which further complicates quantification and budgeting but does favor integration over parallel supply systems. At the facility level, the pressure of the existing workload is already taxing laboratory staff, equipment, and systems. Laboratory staff typically lack the necessary training, management support, financial allocations, and tools to manage supplies effectively.

### **Points to Remember for a Successful Approach**

**Strengthening supply management at the laboratory requires time and a stepwise approach.** Laboratory assessments usually reveal numerous commodity management problems and may require some operations to be set up from scratch. Focusing initial activities on the most critical and essential tests needed to support HIV/AIDS

programs, in addition to prioritizing interventions, enables implementers to establish working systems sooner and to gradually expand them to include a wider range of products and services.

**Including management staff in commodity management training for laboratory staff enables them to support and ensure efficient use of the laboratory.** Strategies to improve the performance of the laboratory commodity management system at the facility level are generally more effective when management and laboratory staff work together to solve problems. This is particularly true for problems related to procurement.

**Priority interventions should include strengthening of inventory management at the facility level.** Training facility staff in good storage practices and basic inventory management (e.g., introducing stock cards, reorganizing the storeroom, removing obsolete equipment and expired stock) is an essential first step.

**A consultative process is needed to standardize laboratory testing requirements for HIV/AIDS programs. The tests and equipment that will be available at each level of health facility should be agreed upon as part of an overall national strategic plan.** Although the process can take time, this step is critical to enable procurement staff to quantify needs and develop a procurement

and distribution plan. Once agreement is reached, implementation can take time as products work their way through the pipeline. A decision will also need to be made on whether to keep or discard nonstandard equipment currently in use. At the facility level, clinical algorithms for laboratory monitoring should be standardized, and adherence to these standards should be monitored.

**Selection and specifications of laboratory equipment should consider the needs of infants and children, where appropriate.** For example, laboratory equipment may need to have the capacity to analyze small-volume samples, and CD4 technologies that provide percentage readings may be required.

**Where usage data are not available and quantification is based on standard protocols and projected client visits, requirements for quality control, calibration of equipment, training, and wastage will need to be incorporated.** If the reagents are used for non-HIV/AIDS purposes, estimates will need to incorporate other uses to avoid stock-outs. Establishing a system to collect consumption data is a priority, particularly at laboratories that serve many sites and a large number of external clients. In such cases, using projected client visits to estimate reagent and supply needs can be especially problematic.

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