CHAPTER 18

Managing procurement

SUMMARY

This chapter focuses primarily on best practices for health systems that manage procurement in-house. An effective procurement process seeks to ensure the availability of the right medicines in the right quantities, at reasonable prices, and at recognized standards of quality. Pharmaceuticals may be acquired through purchase, donation, or manufacture.

The procurement cycle involves the following steps—

- Mobilize procurement team and key players
- Review medicine selections
- Specify quality standards
- Determine quantities needed
- Reconcile needs and funds
- Choose procurement method
- Locate and select suppliers
- Specify contract terms
- Monitor order status
- Receive and check medicines
- Make payment
- Distribute medicines
- Collect consumption information

The major procurement methods used by health systems are open tender, restricted tender, competitive negotiation, and direct procurement, which vary with respect to their effect on price, delivery times, and workload of the procurement office. In recent years, some public-sector procurement systems (particularly in Latin America) have introduced e-procurement (Internet tendering) and more specifically the "reverse auction" approach, although these methods have not been widely used to procure pharmaceuticals. Funding sources (governments and donors) often dictate which procurement method to use. Finally, some developing-country health systems purchase medicines and health commodities directly from international procurement agents, many of which are based in Europe.

Key principles of good pharmaceutical procurement for health systems include—

- Reliable payment and good financial management
- Procurement by generic name
- Clear specification of a recognized pharmaceutical quality standard
- Limitation of procurement to the essential medicines list
- Increasing procurement volume by aggregating demand
- Formal supplier qualification and monitoring
- Competitive procurement
- Monopsony commitment
- Order quantities based on reliable estimate of forecasted actual need
- Transparency and written procedures
- Separation of key functions
- Product quality assurance program
- Annual audit with published results
- Regular reporting of procurement performance indicators

As described in Chapter 8, different systems for managing supply chains for public health systems include the central stores system, autonomous supply agency system, direct delivery system, primary distributor system, private pharmacy system, or often a mix of these systems. All involve pharmaceutical procurement.

Procurement may proceed under different purchasing models—annual purchasing, scheduled purchasing, or perpetual purchasing. Different combinations of these models may be used at different levels of the system or for different medicines.

Effective procurement is a mechanism for managing the buyer-seller relationship to ensure transparent and ethical transactions that result in the buyer receiving the correct goods and the seller receiving timely payment. A collaborative process is needed between the procurement office, with requirements for trained staff and appropriate management systems, and technical and policy committees, which may make final decisions as to which medicines to buy, in what quantities, and from which suppliers.

Key considerations for financial sustainability include reliable access to funds for pharmaceutical purchase and support of the procurement office, access to foreign currency exchange for international procurement, and reliable payment mechanisms.

18.1 Introduction

The pharmaceutical procurement system is a major determinant of pharmaceutical availability and total pharmaceutical costs. In most developing countries, pharmaceutical purchases represent the single largest health expenditure after personnel costs. Pharmaceuticals also consume the major share of health-related foreign currency exchange.

An effective procurement process should—

- Seek to manage the buyer-seller relationship in a transparent and ethical manner
- Procure the right medicines in the right quantities
- Obtain the lowest practical purchase price
- Ensure that all pharmaceuticals procured meet recognized standards of quality
- Arrange timely delivery to avoid shortages and stockouts
- Ensure supplier reliability with respect to service and quality
- Set the purchasing schedule, formulas for order quantities, and safety stock levels to achieve the lowest total cost of purchasing at each level of the system
- Achieve these objectives in the most efficient manner possible

Given the impact of procurement activities on the operation and effectiveness of health services, it is essential that these activities be performed by competent staff using sound procedures, working in adequate offices with good communications, and with access to reliable inventory and consumption information. Good procurement management also demands medical, pharmaceutical, managerial, financial, and often political expertise.

Some developing countries have relatively successful public-sector procurement programs, but in many countries, pharmaceutical procurement continues to be less successful, in spite of extensive reform efforts and substantial financial assistance from aid agencies.

When a health system sets up a centrally managed pharmaceutical procurement program, it is, in effect, developing a form of a pooled procurement system serving health regions, districts, and individual health facilities. The purchases may be financed centrally through government allocations or donor contributions, in a decentralized way through medicines fees, or through some combination of financing alternatives. Procurement may be managed through any of several organizational arrangements described in Chapter 8 and discussed later in this chapter.

Over the last twenty years, formal pooled procurement programs have become common in some industrialized countries (known in the United States as group purchasing organizations), and the factors that make them successful are known. Regional approaches to multicountry pooled procurement have had mixed results, although there are some long-standing regional programs that have achieved some successes. At the global level, United Nations agencies such as UNICEF, United Nations Population Fund, and United Nations Development Programme have long functioned as pooled procurement systems serving their country programs. In recent years, a number of new global procurement mechanisms have emerged, such as the Stop TB Global Drug Facility, the U.S. President's Plan for Emergency AIDS Relief (PEPFAR)–funded Supply Chain Management System (SCMS), and the Global Fund to Fight AIDS, Tuberculosis and Malaria's voluntary pooled procurement system.

Although the procurement chapters in this manual are written primarily with public-sector procurement programs in mind, the principles and procedures can be applied to either public or private procurement at any level, from a rural aid post to a national health program. The details of procurement at various levels may be slightly different, but the basic steps are the same.

18.2 The procurement cycle

The procurement cycle includes most of the decisions and actions that determine the specific medicine quantities obtained, prices paid, and quality of medicines received.

Procurement is defined here as the process of purchasing supplies directly from national or multinational private or public suppliers; purchasing through global agencies and procurement mechanisms or regional procurement systems; or purchasing from international procurement agents. These sources may be used individually or in combination to meet the entire range of pharmaceutical needs.

Steps in the procurement cycle are illustrated in Figure 18-1 and discussed in Chapters 9–15 and 18–21.

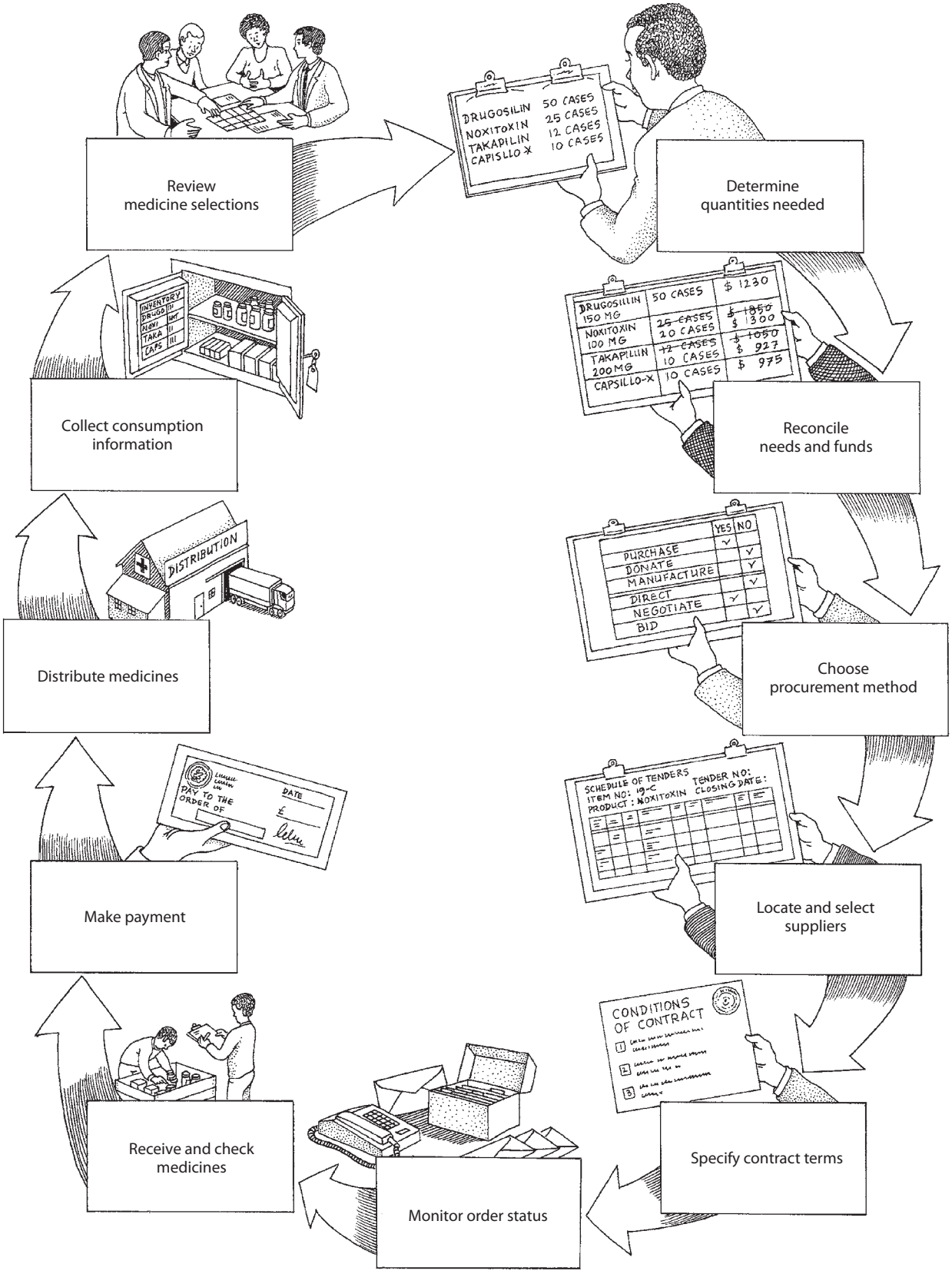
18.3 Factors influencing pharmaceutical prices and total costs

Given the limited budgets of virtually all health programs, pharmaceutical procurement costs must be a concern of all policy makers, senior officials, essential medicines program managers, and procurement staff. Pharmaceutical procurement costs include several different components; some costs are obvious and some are not.

Unit prices

What determines the tender price of a container of 1,000 amoxicilline tablets or ten ampoules of adrenaline? There are many considerations involved in pharmaceutical pricing by manufacturers and distributors, and many factors that

Figure 18-1 Procurement cycle



cause prices to vary from country to country. A fundamental principle is that increasing competition among suppliers and products usually decreases pharmaceutical prices.

Several factors influence competition and pricing in any pharmaceutical market. One issue is how many different drug products and different generic versions of the same product are on the market. The "rule of five" in pharmaceutical pricing says that in general the lowest competitive prices are available when five or more generic alternatives for a particular product are available or when, in a tender, there are at least five bids per item (WHO 1999).

These factors can be influenced by government policies on registration, licensing for manufacturing and distribution, authority to prescribe and dispense, generic substitution, and price control. In some markets, even sole-source suppliers may offer discount pricing to the public sector that is not necessarily related to purchase volume to establish or maintain market share or to negotiate with international development entities. As discussed in Section 18.4, the type of procurement method used greatly influences how much competition there is among potential suppliers. The strategies and issues discussed in Section 18.5 also directly or indirectly influence the degree of competition and the degree of discount pricing available to the health system.

Reorder frequency and the total cost of purchasing

Pharmaceutical acquisition prices are only one part of the total cost of pharmaceutical purchasing; the other important components are the costs associated with holding inventory, the costs of operating the purchasing system, and the extra costs incurred when stockouts occur (shortage costs).

Although procurement offices typically concern themselves mainly with pharmaceutical acquisition costs, the other cost components may increase the total purchasing cost by 50 percent or more of the acquisition costs. For each country's situation, total purchasing costs can be minimized by choosing the optimal reorder frequency model, as defined by the—

- Interval between orders—options include annual (one order per year), scheduled (periodic orders, for example, every three months), and perpetual (orders placed whenever stock falls to a specified level)
- Safety stock targets, which vary according to supplier lead times, patterns of consumption, and service-level objectives
- Formula used for calculating the order quantity, which may be a fixed or variable quantity

The choice of reorder frequency models is discussed in Chapter 23; these are not always simple decisions. Systems minimize costs by striking the right balance between the various elements—less frequent ordering decreases procurement process costs, but increases stock-holding costs. The reorder frequency model may differ from one level of the supply system to another or from one type or class of drug product to another. For example, consider a supply system with a central medical store (CMS) and several regional warehouses that serve hospitals and major health centers, which then distribute to primary care facilities. The CMS might purchase most items through annual tender; however, most countries can achieve lower total costs by purchasing at least some items more frequently. The regional stores might order from the CMS on a quarterly basis for most items. The health centers and hospitals might order most items monthly, with a weekly supplemental order, and so forth.

The reorder frequency influences the types of procurement methods and purchasing contracts that can be used (see Section 18.4). However, this works both ways; individual country circumstances (typically storage conditions and space availability) or laws and funding regulations, especially from donors, may dictate one sort of procurement method or contract, which then limits the options for choosing the reorder frequency. For example, if only fixed-quantity tenders are allowable under local laws, implementing a perpetual purchasing model will be difficult. If all pharmaceuticals are imported and average lead times are six to nine months, avoiding an annual purchasing system for most items will be a challenge.

The systems and formulas used to estimate needs and define order quantities vary with the purchasing model and with the availability of information on past consumption. The procedures for estimating annual procurement needs are discussed in Chapter 20; with scheduled or perpetual purchasing, order quantity can usually be determined by one of the formulas from Chapter 23. However, some situations may require the use of a procedure such as morbidity-based forecasting to estimate needs for procurement (Chapter 20).

Chapter 40 presents total cost analysis as a method for compiling and analyzing the total costs of inventory management: pharmaceutical acquisition, inventory holding, purchasing operations, and shortage costs. Total cost analysis examines stable and variable costs for potential savings and helps managers evaluate potential changes in supply chain structure, and in procurement and distribution policy and procedure, in terms of the likely impact on total operating costs.

Visible and hidden costs

As discussed above, the total procurement cost has four components—pharmaceutical acquisition prices, inventory-holding costs, purchasing operations costs, and shortage costs. Some of these costs are easily visible to managers—the total expenditures for pharmaceutical acquisition or the

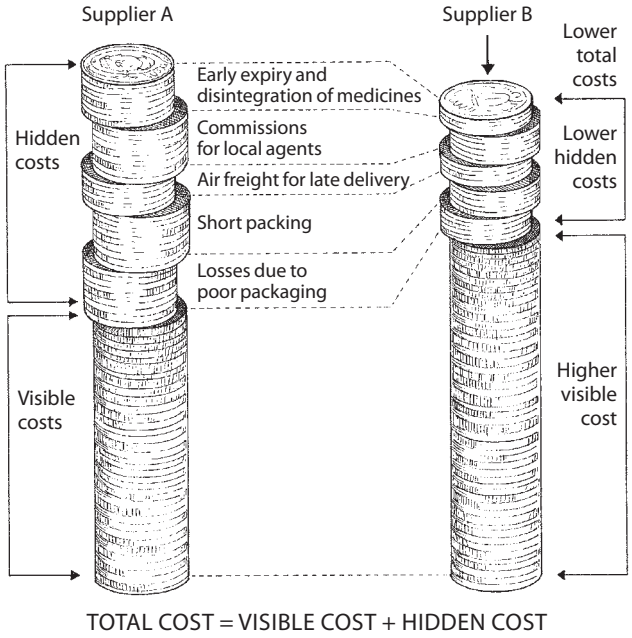
salaries of procurement staff. However, the costs associated with shortages and poor supplier performance are not so obvious; hidden costs associated with poor performance by the supplier or the procurement office include—

- Increased acquisition costs due to emergency procurement, such as when a vital medicine is ordered too late or usage exceeds estimates or the supplier fails to deliver on time
- Replacement costs when goods are lost or must be discarded because of poor packaging, improper shipping conditions, rapid spoilage, or short shelf life
- Replacement costs for short shipments, incorrect concentrations of liquid preparations, wrong dosage forms, and so on
- Storage, port charges, and administrative expenses due to inefficient clearing procedures or lack of funds or proper documentation
- Health and economic costs of stockouts resulting from delay or default on delivery

The potential impact of hidden costs on the total cost is illustrated in Figure 18-2. In this example, supplier A has quoted a lower price, but additional expenses resulting from poor performance ultimately raise the total cost above that quoted by supplier B. In a competitive tender, a large number of suppliers with varying technical and commercial backgrounds may submit bids, and their quoted prices will vary considerably. Because no cost adjustments for performance are permitted to be considered during the tender assessment process, once tender bidding has begun, the prequalification of suppliers based on past performance can help minimize the impact of hidden costs.

Many of the hidden costs mentioned above can be minimized through careful procurement practices, such as avoiding last-minute orders due to a lack of planning; however, other hidden costs are imposed or regulated by the government, which may be more difficult for the procurement office to work around. Country Study 18-1 shows examples of hidden costs of medicines that are controlled through national pharmaceutical policy. See also Chapter 9 on pharmaceutical pricing.

Figure 18-2 Impact of hidden cost on total cost



18.4 Overview of procurement methods

There are numerous mechanisms by which governments, nongovernmental organizations (NGOs), and other organizations manage their in-house procurement of pharmaceuticals. Pharmaceutical procurement methods, at any level of a health system, generally fall into a few basic categories: open tender; restricted tender; competitive negotiation, including international or local shopping; and direct procurement. Each of these methods can be used with any of the standard reorder frequency models—annual, scheduled, or perpetual review—given the right sort of procurement contract.

Open tender: Open tendering is a formal procedure by which quotes are invited from any supplier's representative on a local or worldwide basis, subject to the terms and conditions specified in the tender invitation. International competitive bidding, as specified in World Bank (2000; 2004b) guidelines, is a tender open to all interested international manufacturers from World Bank member countries.

Restricted tender: In a restricted tender, interested suppliers must be approved in advance, often through a formal prequalification process that considers adherence to good manufacturing practices, past supply performance, financial viability, and related factors. The prequalification process is often open to any supplier that wishes to apply.

E-procurement and reverse auction: E-procurement is Internet-based tendering. In the reverse auction approach (which is a variation of restricted tenders), qualified bidders submit an initial offer; the lowest offer received is posted publicly without naming the bidder after the first round; and then qualified bidders are invited to offer lower prices than that posted low price. The process continues round-by-round until no more prices are submitted; then the lowest posted bid wins the contract. This approach has rarely been used for pharmaceutical procurement (with most experience in Latin America); however, it may gain traction as global Internet capacity and use increase. Pharmaceutical qual-

ity assurance requirements and related factors may limit the use of this model, at least in its current form.

Competitive negotiation: In competitive negotiation, the buyer approaches a limited number of selected suppliers (typically at least three) for price quotations. Buyers may also bargain with these suppliers to achieve specific price or service arrangements. This procurement method is used primarily in the private sector, because public-sector procurement organizations are generally forbidden from negotiating or bargaining with suppliers. For example, global organizations such as UNICEF, the Clinton Foundation, and SCMS have successfully negotiated reduced prices of antiretroviral (ARV) medicines with manufacturers.

International or local shopping: As with competitive negotiation, in international or local shopping, the buyer obtains at least three quotes from suppliers; however, bargaining or negotiation of any kind are generally not permitted.

Direct procurement: The simplest, but usually most expensive, method of procurement is direct purchase from a single supplier, either at the quoted list price or at a negotiated standard discount off the list price. For single-source medicines (generally those under patent with no licensing agreements that allow other firms to manufacture the medicine), the buyer basically has three choices—negotiated procurement, direct procurement, or selection of an alternative drug product.

International open tenders usually attract the largest number of competitive offers and potentially the lowest prices. International tenders for pharmaceuticals are limited to primary manufacturers and commercial suppliers or to international procurement agencies.

Virtually all professionally managed pharmaceutical procurement offices (that is, international procurement agencies and successful government pharmaceutical procurement units) purchase most large-volume items by either restricted tender or competitive negotiation from a limited list of reliable suppliers, such as private companies and global procurement mechanisms such as SCMS, the Global Fund's voluntary pooled procurement, or UNICEF.

Some procurement offices use a combination of methods: open or restricted tender for large-volume items, and competitive negotiation or direct procurement for lower-volume or emergency supplies.

In many country situations it may not be feasible or cost-effective to satisfy demand for medicines and obtain

Country Study 18-1
Hidden costs in the procurement process: Examples from nine countries

Understanding the many component costs related to procuring medicines is an important step in reducing overall costs. Improving procurement practices can help decrease hidden costs, but many costs result from government policies. In a study of the hidden costs of essential medicines, information on such government-influenced tariffs and charges was collected from the literature and through personal communication. The table below shows the extensive variation and potential impact that these types of costs can have on prices of essential medicines—which may be passed along to patients.

Source: Adapted from Levison and Laing 2003.

	Percentage added to prices of essential medicines								
Hidden cost	**Sri Lanka**	**Kenya**	**Tanzania**	**South Africa**	**Brazil**	**Armenia**	**Kosovo**	**Nepal**	**Mauritius**
Import tariff	0	0	10		11.7	0	1	4	5
Port charges	4	8	1				4		
Clearance and freight		1	2					1.5	5
Preshipment inspection		2.75	1.2						
Pharmacy board fee			2						
Importer's margins	25						15	10	
Value added tax				14	18	20	0		
State government tax					6				
Wholesaler	8.5	15	0	21.2	7	25	15	10	14
Retail	16.25	20	50	50	22	25	25	16	27
Total markup	**63.97**	**54.22**	**74.3**	**74.05**	**82.38**	**87.5**	**73.64**	**48.08**	**59.26**

Country Study 18-2
Pooled procurement through the Organisation of Eastern Caribbean States/ Pharmaceutical Procurement Service

The Pharmaceutical Procurement Service (PPS) (originally known as the Eastern Caribbean Drug Service) was established in 1986, with U.S. Agency for International Development (USAID) support, to manage the procurement process on behalf of member countries of the Organisation of Eastern Caribbean States (OECS).

Before the OECS/PPS, the pharmaceutical supply systems of OECS member countries were beset with problems: disorganized procurement and management functions and poorly trained staff contributed to chronic medicine shortages in health facilities. Because of fiscal constraints, countries were slow to make payments to suppliers and incurred large surcharges. The pharmaceutical prices paid by OECS states ranged 30 percent or more above those paid by other countries of the Caribbean, such as Barbados.

Design of the OECS/PPS procurement program incorporated a number of key features—

Selective list: Procurement under OECS/PPS is based on the *Eastern Caribbean Regional Drug Formulary and Therapeutics Manual,* compiled from individual country medicine lists representing large-volume items for which demand is consistently high. The OECS/PPS procures approximately 80 percent of public-sector pharmaceuticals and medical supplies. Country-level purchasing officers may purchase nontender items independently.

Pooled quantities: Each year, the nine participating countries project their expected purchases of formulary items and forward these estimates to OECS/PPS, where management and technical staff review them. The individual projections are then aggregated into a single tender list.

Competitive bidding: Suppliers are prequalified for the OECS/PPS restricted tenders. Prequalification is based on submission of a vendor registration form and reference checks with international agencies and procurement agencies that are listed as references. A single contract award is made for each tendered product to a primary and a secondary supplier. Unless quality or performance issues are a concern, the lowest tender price receives the primary award. Tenders are not split.

Supplier monitoring and quality assurance: The performance of all contract suppliers (lead times, partial shipments, quality problems) is monitored and reviewed annually to determine which suppliers should continue as registered participants. OECS/PPS solicits oral and written reports from member countries concerning potential product problems and follows up with testing at the Caribbean Regional Drug Testing Laboratory.

Variable purchase quantities by group members: OECS/PPS estimates of purchase volume are not binding on individual countries or on OECS/PPS, and no

competitive pricing entirely through locally managed procurement. There are global as well as some regional procurement sources that can be accessed to augment, or if needed, to replace locally managed procurement for a selected set of products.

At the global level, United Nations agencies such as UNICEF have long operated pooled procurement systems primarily serving their own country programs. In recent years, several other global pooled procurement mechanisms have emerged along with the large increase in funding for procurement through financing mechanisms such as the Global Fund, UNITAID, and PEPFAR. Moreover, a number of nonprofit procurement agencies serve as suppliers to public and NGO health systems in developing countries; while these are not pooled procurement mechanisms per se, they do offer relatively small-scale purchasers access to "global" pricing.

Generally, three types of these global procurement mechanisms exist—

Integrated "local-to-global" supply chain systems: These mechanisms work directly with countries to coordinate demand and manage tenders and competitive negotiations to establish best prices; manage global freight and logistics systems to coordinate distribution; and operate in-house product quality assurance programs. The best known such mechanism is probably the UNICEF system. In addition, SCMS now provides HIV-related commodities and services to countries that receive PEPFAR funding.

Donor-supported global procurement agencies: Examples include the Stop TB/WHO Global Drug Facility, which purchases and distributes both first-line and second-line TB medicines, and the Global Fund's voluntary pooled procurement mechanism, which purchases and delivers medicines and other health commodities to Global Fund principal recipients.

Nonprofit procurement agencies: These agencies purchase and distribute medicines and other health commodities

fixed procurement quantity or delivery schedule exists. All OECS member states are charged the same contract price, regardless of volume, for the duration of the contract period. All tender prices are CIF (cost, insurance, and freight) direct to the member country.

Monopsony commitment: Member countries are required to purchase items listed in OECS/PPS contracts solely through the PPS system, from contracted suppliers. OECS/PPS monitors this requirement annually.

Reliable payment mechanism: Payments to suppliers are managed by the Eastern Caribbean Central Bank (ECCB), where each participating country maintains a special revolving drug account. Suppliers are paid directly by the ECCB from the purchasing country's drug account, and the individual countries reimburse their accounts when they receive their shipments. An important element in PPS's initial success in pooling procurement was its ability to pay suppliers promptly in foreign exchange within sixty days of receipt in country. However, in recent years, some OECS countries have been slow to reimburse their country drug accounts, resulting in suppliers withholding shipments to both the late and the on-time payers. An additional consequence has been the dwindling number of suppliers competing in the tendering process, which can discourage the lowest prices in competitive bidding.

Thirteen-percent fee to group members: With each order, an administrative fee of 13 percent of the payment amount is made by ECCB to the PPS account. (The fee was originally 15 percent.) This fee covers all PPS operating expenses; no additional budget allocations have been required. OECS/PPS became financially self-supporting in 1989.

The results of the OECS/PPS procurement program have been extremely positive. After initial success with pharmaceuticals, the PPS has expanded its list of tendered products to include medical supplies, contraceptives, and x-ray consumables. It includes 700 items—about 70 percent of them pharmaceuticals. Participating countries benefited from an average 44 percent reduction in acquisition price for tender products in the first OECS/PPS tender cycle (1987–88) and an average of 37 percent between 1998 and 2002. Between 1997 and 2006, the value of annual purchases increased by more than 100 percent.

The main challenges include late payments by member countries, the opposition and influence of suppliers, countries making purchases outside of the cartel, managing donations, poor forecasting, and small purchase orders.

Sources: Burnett 2003; WHO 2007.

to public sector and NGO health systems in developing countries. Such agencies are often, but not always donor financed. Examples include Action Medeor, IDA Foundation, MissionPharma, and Trimed.

Regional multicountry pooled procurement has been attempted over the years in different parts of the world, but has rarely proven sustainable. However, some regional systems have achieved successes over time, including the Pooled Procurement Service (PPS) of the Organisation of Eastern Caribbean States (OECS), the Gulf Cooperation Council group purchasing program, and the Pan American Health Organization (PAHO) regional programs for purchasing vaccines and ARVs.

Undoubtedly, the primary consideration in developing a pooled procurement system is political commitment; without it, the system will never succeed. But even with political commitment, several aspects of procurement need to be harmonized for successful implementation of multicountry pooled procurement mechanisms. They include laws, regulations, and operational processes related to—

- Medicines regulation and registration of products
- Procurement processes and local preference issues
- Financial mechanisms and payment to vendors
- Standard currency

The difficulty in harmonizing these processes should not be discounted, and some issues also affect global pooled procurement mechanisms. For example, the lack of harmonization among national registration requirements often limits the capacity of a global pooled procurement system to establish supply contracts that will serve all target countries, because the best-value supplier may not have registered its products in all of the countries. Over the years, regional groups, such as the Association of Southeast Asian Nations and the Pan American Network for Drug Regulatory Harmonization have worked to formalize pharmaceutical harmonization initiatives, often focused on pharmaceutical registration, and sometimes on procurement policies and regulations (see Country Study 18-2).

Four models of procurement collaboration include informed buying, coordinated informed buying, group contracting, and central contracting and purchasing (MSH/CPM 2002). Regional pooled procurement does not have to start with a full-fledged pooled procurement system. The first step might be simple information sharing between national or subnational procurement agencies. If

Country Study 18-3
Assessing regional collaboration of procurement activities to increase access to HIV/AIDS medicines and commodities in sub-Saharan Africa

Sub-Saharan Africa faces challenges in increasing access to high-quality, affordable pharmaceuticals for treating people living with HIV/AIDS. Even when antiretroviral treatment is available, its effectiveness is undermined by lack of access to a constant and uninterrupted supply of antiretroviral medicines. Groups of countries in different parts of the developing world have had success in pooling their resources to more efficiently procure essential medicines and supplies. Regional collaboration for the procurement of HIV/AIDS-related pharmaceuticals and commodities was proposed as a way to increase access to these products in the fourteen countries belonging to the Commonwealth Regional Health Community (CRHC) of East, Central, and Southern Africa.

Regional collaboration for procurement

Collaborative procurement covers a range of options, from simple information sharing to pooling of resources, combined with contracting and purchasing by an agency acting on behalf of a group of facilities, health systems, or countries. The four models of collaboration assessed are informed buying, coordinated informed buying, group contracting, and central contracting.

Information sharing		Pooled procurement	
Informed buying	**Coordinated informed buying**	**Group contracting**	**Central contracting and purchasing**
Member countries share information about prices and suppliers.	Member countries undertake joint market research, share supplier performance information, and monitor prices.	Member countries jointly negotiate prices and select suppliers. Member countries agree to purchase from selected suppliers.	Member countries jointly conduct tenders and awards contracts through an organization acting on their behalf.
Countries conduct procurement individually.	Countries conduct procurement individually.	Countries conduct purchasing individually.	Central buying unit manages the purchase on behalf of countries.

all the requirements to sustain an effective and efficient formal pooled procurement system can be met, the group can progress to pooling resources combined with joint contracting and purchasing carried out by an agency acting on behalf of a group of facilities, health systems, or countries. Country Study 18-3 summarizes an assessment of countries in sub-Saharan Africa that was done to determine if a regional collaboration model for procurement was feasible.

In many countries, laws and government regulations or the funding sources (that is, donors) dictate the procurement method to be used, often based on the value of the goods being purchased. Chapter 21 focuses on the tender process and compares the most common procurement methods.

18.5 Good pharmaceutical procurement practices

Pharmaceutical procurement practices vary widely from country to country. However, decades of experience with essential medicines programs and many more years of experience with large government-run pharmaceutical supply services in a number of countries, as well as with regional and global pooled procurement schemes, have suggested a number of key principles, which Box 18-1 summarizes. These practices are applicable to individual procurement agencies as well as to pooled procurement systems serving multiple health systems.

Reliable payment and good financial management

Prompt, reliable payment of suppliers has the single greatest influence on bringing down pharmaceutical prices and keeping those prices as low as possible (see Country Study 18-2), but this area often receives inadequate attention. Given greater needs and limited resources, donors and funding agencies are increasingly disbursing funds more readily to health programs with a history of strong financial management, and in some cases, *only* to countries that have strong financial management records.

Financial mechanisms such as decentralized, dedicated pharmaceutical purchasing accounts may allow the procurement cycle to operate independently from the treasury cycle. Revolving pharmaceutical funds can help achieve this separation by establishing their own bank accounts and their own working capital.

Assessment

The Rational Pharmaceutical Management (RPM) Plus Program of Management Sciences for Health administered a questionnaire to assess the structure of public-sector pharmaceutical management to support pooled procurement in eleven CRHC member states: Kenya, Lesotho, Malawi, Mauritius, Mozambique, Seychelles, Swaziland, Tanzania, Uganda, Zambia, and Zimbabwe. Before this study, no standardized approach had been used to guide groups of countries in selecting the best model for collaboration. The methodology identifies favorable conditions that point a group of countries toward a particular model, based on the group's characteristics.

Assessment results

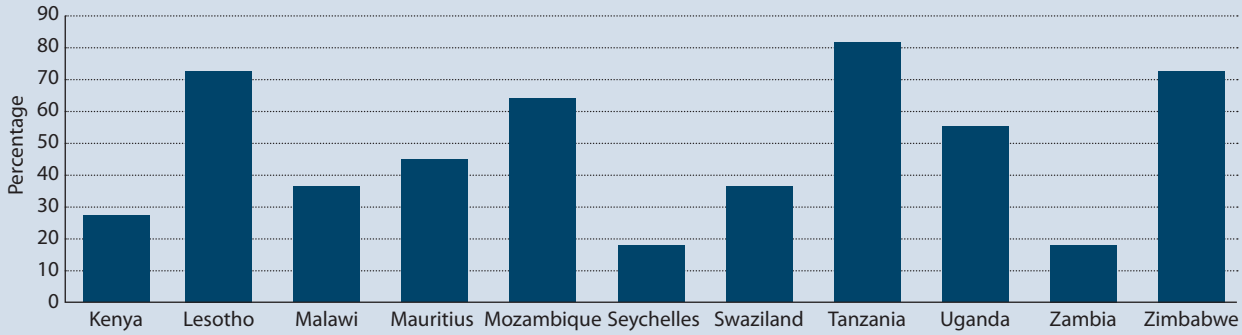
The assessment results showed that three countries—Lesotho, Tanzania, and Zimbabwe—representing 27 percent of countries studied, appeared ready to initiate coordinated informed buying. This method of collaboration for procurement requires dedicated human resources and a budget to conduct market research on pharmaceutical suppliers. A number of countries do not currently have the needed resources, resulting in the small proportion of countries ready to start this mode of collaboration.

Coordinated informed buying strategy

- Creating a mechanism for the collection, analysis, storage, and dissemination of information on HIV/AIDS-related pharmaceuticals and commodities
- Creating awareness of coordinated informed buying among decision makers and other relevant bodies
- Developing capacity within member states to conduct informed buying-related market research
- Setting up and operating a coordinated informed buying system within the CRHC member states
- Monitoring program execution

Source: MSH/RPM Plus 2004.

Readiness of countries to undertake coordinated informed buying



Efficient financial management systems are especially important if funds are limited and procurement priorities must be closely managed. Being able to order pharmaceuticals when needed and to pay for them on time reduces both prices and stockouts.

Procurement by generic name (International Nonproprietary Name)

Procurement by generic name—formally known as the International Nonproprietary Name (INN)—has become the standard for purchasing pharmaceuticals that are available from multiple companies. Brand-name suppliers may compete, but their bids should be by generic name; they may offer lower prices for certain medicines than generic competitors, because they wish to keep their public-sector market share. Perhaps the most impressive achievement in recent years is the dramatic reduction in worldwide prices of ARVs, which has led to a surge in patients who can receive life-saving treatment. This price reduction has largely been driven by procurement of generics, which has been well documented (Holmes et al. 2010). All pharmaceuticals supplied to the health system should be labeled with the INN featured prominently, in addition to any brand name that may be on the label. For more information on INNs see http://www.who.int/medicines/services/inn/en.

Procurement limited to essential medicines list or formulary list

Virtually no health program can afford to purchase all pharmaceuticals available on the market. A limited medicine list or formulary, defining which medicines will be purchased, is one of the most effective ways to control procurement costs. It simplifies other supply management activities and reduces inventory-holding costs as well (see Chapter 23).

The first step is to avoid generic duplication; after this, two main options exist for reducing the procurement list. The

Box 18-1
Good pharmaceutical procurement principles

Reliable payment and good financial management

- Develop mechanisms for prompt, reliable payment, which might bring down pharmaceutical prices more than bulk discounts.
- Establish financial mechanisms with separate pharmaceutical accounts (for example, revolving drug funds) to allow the procurement cycle to operate on a separate schedule from the treasury cycle.

Procurement by generic name

- Use generic names (International Nonproprietary Names) for fair competition.
- Specify quality standards, not specific brands, for medicines with bioavailability problems.

Procurement limited to essential medicines list or formulary list

- Select safe, effective, cost-effective medicines.
- Use formal approval procedures for procurement of nonlisted medicines.

Procurement in large volume

- Concentrate purchases on limited list to increase quantities, reduce price.
- Specify divided deliveries

Formal supplier qualification and monitoring

- Use formal supplier qualification based on pharmaceutical quality, service reliability, and financial viability.
- Approve suppliers before tendering (prequalification) or after (postqualification).
- Use a formal monitoring system to ensure continued supplier qualification.

Competitive procurement

- Use competitive bidding on all but very small or emergency purchases to obtain the best prices.
- Allow only prequalified suppliers to compete in restrictive tenders.
- Evaluate suppliers after submission of bids in open tenders.

Monopsony commitment

- Procure all contracted pharmaceuticals from winning supplier.
- Enter into no separate deals with noncontracted suppliers.

Order quantities based on reliable estimate of actual need

- Develop reliable consumption records and morbidity data.
- Adjust systematically for past surpluses, shortages, stockouts.
- Adjust for expected program growth and changing disease patterns.

Transparency and written procedures

- Develop and follow written procedures for all procurement actions.
- Make information on the tender process and results public to the maximum extent possible.

Separation of key functions

- Separate key functions that require different expertise.
- Functions that involve different committees, units, or individuals may include selection, quantification, approval of suppliers, and award of contracts.

Product quality assurance program

- Establish and maintain a formal system for product quality assurance.
- Include quality assurance product certification, inspection of shipments, targeted laboratory testing, and reporting of suspect products.

Annual financial audit with published results

- Conduct an annual financial audit to assess compliance with procurement procedures, promptness of payment, and related factors.
- Present results to the appropriate public supervising body.

Regular reporting on procurement performance

- Report key procurement performance indicators against targets at least annually.
- Use key indicators such as ratio of prices to world market prices, supplier lead times, percentage of purchases made through competitive tendering, and planned versus actual purchases.

first combines the standard formulary process (Chapter 16) with therapeutic category analysis (Chapter 40). For example, a program that regularly purchases cimetidine, famotidine, and ranitidine (all therapeutically similar anti-ulcer medicines) might save substantial sums by restricting the formulary to one of these medicines and combining the estimated purchase volume into a single, much larger quantity of the selected medicine.

The second approach takes formulary selection and therapeutic category analysis one step further through competitive tender within a selected therapeutic subcategory (Chapter 40). The medicine selection committee determines which subcategories are appropriate for category-based tendering and which medicines in those subcategories are acceptable equivalents. The tender request specifies only the therapeutic category rather than individual drug products. This strategy has been used for several years in some purchasing groups in the United States and in the OECS and is similar to strategies used in Europe for establishing reimbursement prices.

Any change from one therapeutically similar product to another should be carefully considered, particularly for medicines used in chronic treatment; patients using these medicines need to be monitored during the changeover, which can generate significant costs for care and treatment.

Efforts to limit the medicine list by reducing therapeutic duplications will meet resistance both from pharmaceutical suppliers whose products are removed from the procurement list and from some doctors and some patients who prefer a wider range of choices. Suppliers may issue dire public warnings of adverse impact on public health and patient care if their pharmaceuticals are not purchased. The health system needs to be prepared to counter these claims with carefully designed information campaigns.

Resistance from doctors can often be overcome by documenting the cost savings possible with the restricted procurement list and pointing out the benefits of year-round access to the limited list rather than sporadic access to a larger list of medicines.

Increasing procurement volume by aggregating demand

One of the essential characteristics of pooled procurement is pooling the relatively small demand for a product from each health unit to create a single larger procurement volume for that product. Increasing the total procurement volume for any product increases the likelihood of favorable prices and contract terms as long as there is sufficient competition in the market. Moreover, increasing procurement volume typically increases the number of potentially interested suppliers who wish to win the business, and increases the loyalty and responsiveness of suppliers who win contracts. When the market is tight for a particular product or set of products and available supplies are not adequate to meet global demand, the larger purchasers typically get first preference from suppliers.

However, simply increasing procurement volume may not necessarily assure low prices; one recent analysis of global pricing of ARVs did not correlate volume and price for nineteen of twenty-four dosage forms (Waning et al. 2009), and a study of e-procurement reverse auctions (although not pharmaceutical procurement) also could not link product volume with reduced pricing (Shalev and Asbjornsen 2010). However, in most circumstances, when procuring generically available medications with multiple suppliers, greater procurement volume will attract more competitive offers.

At the national or subnational levels, pooling procurement volume from many facilities or from several states or countries, restricting the medicine list, and eliminating duplication within therapeutic categories lead to higher volumes for single items. In addition, the commitment to awarding a single contract for the entire volume of each item raises suppliers' interest in bidding and provides an incentive for them to offer their most competitive prices.

A contract award to a single supplier does not mean that the entire volume must be shipped at once. Many procurement services specify divided deliveries over the period of the contract as part of the contract terms, sometimes to multiple delivery points. As discussed in Chapter 21, many supply systems use estimated quantity tenders, with orders placed throughout the contract period as needed, using either a scheduled or perpetual purchasing model (see Chapter 23). These strategies allow optimal use of available storage and transport capacity, reduce inventory-holding costs, and ease cash flow constraints.

The potential pricing benefits from a single-supplier award must be compared to the risks to commodity security in the event of unforeseen events (supplier failure, war/civil unrest, industrial disruption, weather events, and other instances of force majeure). In some cases, especially for critical medicines, a risk analysis calls for a secondary supply source. Moreover, when the volume of procurement for individual items represents a significant percentage of the total market for those items, it may be wiser to split contract awards or negotiated contracts among multiple suppliers to preserve future competition and to assure the availability of reliable supply sources if the primary contractor is unable to perform.

Formal supplier qualification and monitoring

All suppliers should be qualified through a process that considers product quality, service reliability and delivery time, and financial viability. The process for evaluating new suppliers can include formal registration, reference checks with past clients and international agencies, test purchases

in small quantities, and informal local information gathering (see Chapter 21). The global procurement mechanisms such as SCMS and Global Fund voluntary pooled procurement may insist that suppliers and their products either be registered by a "stringent regulatory authority" or approved by the WHO prequalification system (Chapter 19).

Although both prequalification (qualifying suppliers before the tender process) and postqualification (qualifying suppliers after bids have been received) have been used in international pharmaceutical procurement, increasingly, health systems and the donors that finance procurement prefer prequalification. In a postqualification system, the procurement office evaluates the suppliers after it receives the bids. Once the tenders are opened, the time window to evaluate and award a contract is limited, which can lead to rushing through the postqualification process. Qualifying suppliers before the tender submission allows enough time for a thorough evaluation. And by first eliminating substandard suppliers from the tender process, prequalification results in a more efficient process by automatically qualifying the lowest-priced bidder.

No matter which supplier qualification model the health system uses, the procurement office needs to make vigorous efforts to assure that purchases come only from suppliers that are known to provide quality products.

Successful procurement operations ensure continued good performance by suppliers through a formal monitoring system that tracks lead time, compliance with contract-pricing terms, partial shipments, remaining shelf life, compliance with packaging and labeling instructions, and compliance with other contract terms. A data file for each supplier, which may be electronic or manual or a combination, should have copies of registration papers, references, special correspondence, complaints, and other anecdotal information. The information system should track the number and value of tender contracts awarded chronologically and the value of total purchases from the supplier by year.

Procurement programs using restricted tenders should make special efforts to seek out potential new suppliers at least every two to three years to maintain competitive pressure on established suppliers.

Competitive procurement

As discussed in Section 18.4, the main methods for purchasing pharmaceuticals are restricted and open tenders, competitive negotiations, and direct purchase from a single-source supplier. Supplier competition is key to favorable pricing, and most modern procurement regulations require competitive procurement in the public sector; therefore, if the needed products have multiple suppliers, then public-sector programs should use competitive bidding for all but very small or emergency purchases. This would not be required when purchasing through a regional or global pooled procurement mechanism because the global or regional procurement office would manage competition.

Monopsony and pooled procurement

A monopsony refers to a situation involving one buyer with many sellers. This is the cornerstone of a pooled procurement system—the group members act as one buyer.

Maintenance of the procurement monopsony will be most feasible when there is strong political will or when all members of the procurement group are voluntarily and enthusiastically participating. Perhaps the single most important factor in the twenty-five-year survival of the multicountry pooled procurement system serving the OECS has been political will and commitment of member governments, although maintaining the monopsony remains a challenge that they must address constantly (see Country Study 18-2).

A review of the two other successful regional pooled procurement programs—the Gulf Cooperation Council and PAHO's vaccine and ARV programs—identified voluntary commitment as a critical factor of their success (DeRoeck et al. 2006). Each program has some flexibility. In the PAHO system, countries choose to participate or not on a yearly basis, and in the Gulf Cooperation Council system, countries are allowed to purchase up to 40 percent of their vaccines outside of the system. But the major point is that once members have committed to purchase a certain percentage or quantity, they are expected to honor that commitment.

On the other hand, the lack of political will to sustain the monopsony commitment is one reason the CARICOM (Caribbean Community) purchasing program for the public sector was unsuccessful in the early 1980s, and it was a major factor in the failure of the FORMED system, which was tried in Central America in the 1990s.

The monopsony commitment should be monitored and enforced. Frequently, local, regional, or multinational suppliers will offer low prices on a short-term basis to individual group members in an attempt to break the purchasing group. A transitory small benefit to one critical group member will adversely affect all other group members, so they must resist these offers; otherwise, suppliers will lose interest in the pooled procurement tenders, the group will fail, and prices overall will rise. Decentralization in some countries has complicated the procurement issue by providing budget funds to lower levels of the health system, to procure their own pharmaceuticals, in addition to the centrally allocated procurement budget. This leads health facilities to purchase from more expensive, but in some cases, more reliable private-sector sources, which leaves the central procurement system with a severe financial shortage because of lost procurement volume (MOH Uganda 2008).

Order quantities based on reliable estimate of actual need

Accurate estimates of procurement volume are needed to avoid stockouts of some pharmaceuticals and overstocks of others in the case of guaranteed quantity contracts. In addition, suppliers are most apt to compete for an estimated-quantity supply contract if they believe that the quantities specified are reasonably accurate.

The most reliable way to quantify future pharmaceutical demand is to start with accurate past-consumption data from all units being supplied, assuming the supply pipeline has been consistently full. These data should be tempered by known or expected changes in morbidity patterns, seasonal factors, service levels, formulary changes or changes to prescribing patterns, and patient attendance. Unfortunately, in many countries, past consumption data are incomplete or do not reflect real need because the supply pipeline has never been full. In such cases, the morbidity-based and adjusted consumption techniques discussed in Chapter 20 may be needed to estimate procurement demand.

Expert technical assistance in quantification may be useful in initial phases of the procurement program, with local officials participating to gain an understanding of the methodology, particularly when applying the morbidity or adjusted consumption methods.

When funds are not available to purchase all the pharmaceuticals listed in estimates, reducing the list according to health system resources is required. The following three tools, discussed in more detail in Chapter 40, can help with prioritization—

VEN (vital, essential, nonessential) analysis classifies medicines in two or three categories, according to how critical the medicines are for treating commonly encountered diseases. Priority is given to vital medicines.

Therapeutic category analysis applies economic analysis of therapeutic choices to help select the best medicines for treating common diseases while minimizing overall cost to the health system.

ABC analysis assembles data from recent or projected procurements to determine where procurement money has actually been spent, allowing managers to focus first on high-cost and high-use items when considering ways to reduce procurement costs.

Transparency and written procedures

The appearance and reality of open and fair competition are essential to attract the best suppliers and the best prices. Fair competition can be achieved by maintaining transparent tender procedures: formal written procedures should be strictly followed throughout the tender, and formal, explicit criteria should be used to make procurement decisions. Broad-based committees should have the sole authority to make contract awards. Information on the tender process and results should be public, to the extent permitted by law and regulation. At a minimum, both bidders and health units should have access to information on the suppliers and the prices for all winning contracts.

When the pharmaceutical tender process is secretive, it tends to be perceived as corrupt or unfair. There may be charges of cronyism. Whether true or not, such charges are damaging in that suppliers, health care providers, and patients lose confidence in the system. Unsuccessful suppliers may feel that they have no chance to win and consequently withdraw from future tenders or submit only token bids. As the pool of potential suppliers decreases to a small set, price competition decreases and procurement prices will be much higher than necessary.

Advocates for increasing the use of e-procurement systems, and particularly e-procurement-mediated reverse auctions, cite transparency and the potential for reduced tender management costs as primary benefits; however, as noted, their effectiveness in widespread application for pooled procurement of pharmaceuticals remains to be seen. One study of public e-procurement in Chile (including all products, not just pharmaceuticals) did not try to compare relative transparency of e-procurement compared with other methods, but it did show a minimal decrease of less than a half of 1 percent in administrative costs when compared with standard methods and less than 3 percent savings through overall price reductions (Singer et al. 2009).

Separation of key functions

There are several key procurement functions, which typically require different expertise. In general, these functions should be handled by different individuals, units, committees, or subcommittees. Such functions include—

- Selection of medicines
- Quantification of pharmaceutical requirements
- Preparation of product specifications and quality standards
- Approval of suppliers (prequalification or post-qualification)
- Adjudication
- Award of tender

Without appropriate separation of functions, the procurement process is much more susceptible to influence by special interests. Suppliers or procurement personnel may be able to bias medicine selection, manipulate orders to increase the quantities of certain medicines, prejudice supplier qualification decisions, manipulate the final award of tender, and slant product specifications to limit competition, for example, by selecting less common dosage forms.

Separation of key functions contributes to professionalism and accountability. Section 18.6 describes ways in which a procurement system can be organized to separate these functions.

Product quality assurance program

An effective procurement program must ensure that the medicines purchased and distributed are of the specified quality, according to specified standards, which are clear and recognized. Chapter 19 discusses three categories of procedures to establish an effective quality assurance system—

- Ensuring that only medicine products that meet current standards for quality are bought
- Verifying that shipped goods meet the specifications
- Monitoring and maintaining the quality of pharmaceuticals from the moment they are received until the medicine is finally consumed by the patient

When managing pharmaceutical procurement by generic name and introducing new suppliers whose products are not familiar in the country, the procurement program must be particularly alert to product quality issues.

Some products vary substantially in formulation and bioavailability from supplier to supplier. When this difference is therapeutically significant, purchasers should be cautious about making changes in supplier from year to year, and particularly in accepting unknown suppliers.

Even when new products are completely equivalent in content and effect, changes in dosage form can be problematic, requiring patient and provider re-education. For medicines used primarily in chronic therapy, changes should only be made to effect a significant cost savings.

Annual audit with published results

At least once a year, the procurement unit should undergo a financial and procurement audit, which is a formal examination and verification of books and records by accountants who specialize in financial audit procedures. *Internal audits* are conducted by auditors from within the government (for the public sector) or the organization managing the health system (for the nonpublic sector). *External audits* are conducted by auditors from outside the managing organization and are generally considered less potentially biased and therefore more credible, even if the process and findings are the same.

The annual external or statutory audit, conducted by a registered or licensed auditor, should include tests to ensure that the organization's assets are safeguarded and accounted for, that the systems of internal controls and procedures are adequate to account for all the organization's income and expenditures, and that the organization is complying with its constitution, rules and regulations, and management. This includes compliance with procurement procedures, promptness of payment, and inventory control.

The auditor should issue a statutory audit report in accordance with legal regulations of the jurisdiction and, in addition, should issue a detailed letter of comment to the management of the organization and to the appropriate public supervisory body.

Regular reporting on procurement performance

Using standard *indicators* to monitor performance and program implementation (see Chapters 36 and 48) significantly improves pharmaceutical management. Standard indicators allow comparison of actual performance with targets, over time and among countries. Some indicators use a standard list of ten to twenty *indicator medicines*, which are also called tracer medicines or a market basket of medicines (Chapter 48).

The procurement office should be required to report on key procurement performance indicators at least annually. The Assessment Guide at the end of this chapter suggests some procurement indicators. Indicators such as average supplier lead time and percentage of key medicines in stock should be used to assess performance on a continuing basis. These indicators should not be limited to the public sector but can be used by all organizations including faith-based pharmaceutical services, NGOs, and private health institutions seeking to control their pharmaceutical costs and improve their performance. Figure 18-3 provides actual indicator data from several countries.

18.6 Organization and management of the procurement and distribution functions

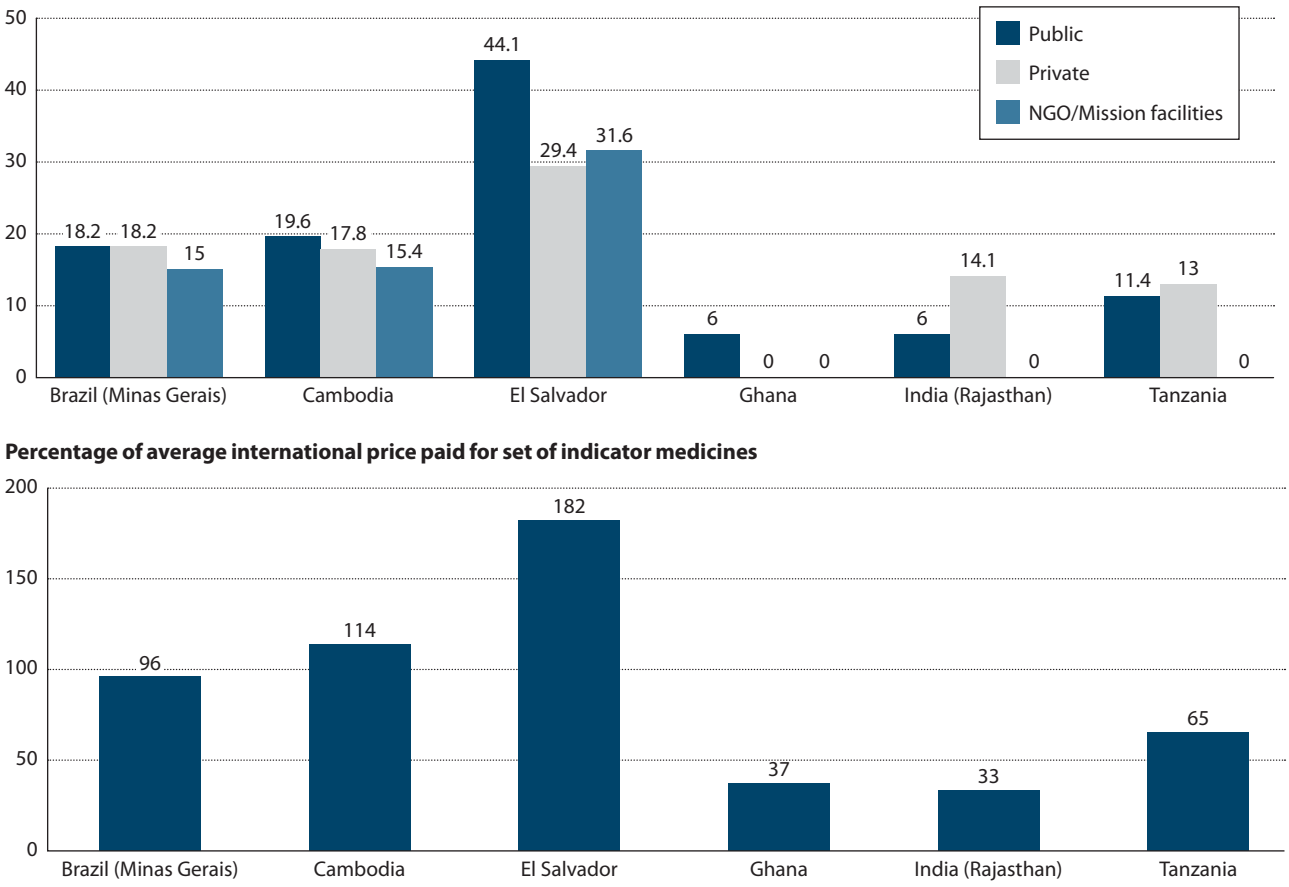
One important policy issue facing senior managers is how to structure the procurement program and supply chain system and how to divide the responsibilities. Chapter 8 describes five different supply chain systems currently being used by governments to supply pharmaceuticals to their health services—

Central stores system: Conventional CMS approach, in which pharmaceuticals are procured and distributed by a centralized government unit.

Autonomous supply agency system: Bulk procurement, storage, and distribution managed by an autonomous or semi-autonomous supply agency, *not* directly managed by the government (although government is often part of the agency's governing board).

Direct delivery system: A "non-CMS" approach, in which tenders establish prices and suppliers for each essential medicine, which is delivered directly by suppliers to individual districts and major facilities.

Figure 18-3 Comparison of two procurement indicator results for six countries



Sources: CPM 2003a, 2003b, 2003c, 2003d, 2003e, 2003f.

Primary distributor system (also known as prime vendor system): contract for pharmaceutical pricing is negotiated with suppliers, and a separate contract is negotiated with one or more primary distributors, who warehouse and distribute pharmaceuticals to districts and major health facilities.

Primarily private supply: Public-sector patients obtain pharmaceutical services from private pharmacies. Government may or may not reimburse the cost of those services, and may also set maximum reimbursable prices including a dispensing fee, minus any co-payments. Reimbursement may go directly to the pharmacy-based on claims submitted, or to the patient (meaning that the patient pays the pharmacy and submits a reimbursement claim).

The important point to a public health system in adapting these alternative supply chain models is to retain the advantages of pooled procurement to the extent feasible. Generally, two common variations exist on managing the purchasing transactions in pooled procurement programs. In both, a single agency manages tenders and contract negotiations on behalf of the group. Then, in a centralized purchasing model the central office also manages the purchasing transactions on behalf of group members, while in a decentralized purchasing model the group members purchase individually from the suppliers who hold the contracts that were centrally negotiated. (See Country Studies 18-2 and 18-3 for examples of group purchasing systems.)

Centralized management of both the purchasing and contracting functions offers some potential advantages—

- Economies of scale reduce the cost of managing procurement offices.
- Sustaining an effective program is easier with only one procurement unit to staff and manage.
- A single procurement list for a large group of facilities increases volume, promotes reduced prices, and improves market presence, which leads to better supply security and quality.

- Better-managed systems of finance and payment may encourage suppliers to compete for contracts and to perform well.

A centralized purchasing system also has potential drawbacks—

- If it does not function well, all group members suffer: although the prices may be theoretically better than with individual members doing the purchasing, the system may not be as responsive and may not provide the medicines needed in time to provide continuous care to patients.
- Without significant input from the participating facilities, centralized purchasing services will likely not meet users' needs very well.
- If the central agency has substantial corruption, the program will never function effectively.

Pharmaceutical purchasing and distribution systems have traditionally been heavily centralized in many developing countries, with little management input from lower levels. Many of these countries are now decentralizing procurement to the regional, state, or even local facility level, either by choice or because the central system has collapsed.

However, decentralized procurement management has proved challenging in many countries. Problems encountered include significantly higher prices (if the decentralized managers select their own suppliers), potential product quality issues, irrational purchasing patterns based on the whims of prescribers or local procurement offices, and overall erratic supply because of local inefficiencies, lack of access to funds, or poor management.

Supervision by senior management

Without political commitment to efficiency and active supervision by senior management, the procurement system will not function efficiently, regardless of its organization. The lack of modern financial management, accounting systems, and supervisory responsibility has doomed many pharmaceutical systems to chronic failure.

To manage the pharmaceutical supply chain, senior managers should demand and use regular reports from procurement and distribution agencies and from health facilities on expenditures, purchases, stock levels, order status, lead times, and budget status. If a system lacks the capacity to produce these reports in a timely manner, introduction of the tools to provide them should be top priority. Senior managers should also maintain regular communications with facilities and staff; systems do not work very well if the senior managers have never visited any facilities outside the capital.

Many operations-level procurement managers have not had formal management training and may fail to appreciate the importance of setting such realistic and quantifiable procurement objectives as—

- Acquiring quality supplies at the best possible price
- Ensuring prompt and dependable delivery
- Following procedures that are transparent and not influenced by special interests
- Maintaining a procurement pattern that produces an even workload and constant supply to clients
- Achieving efficiency through use of appropriate systems and procedures
- Limiting total procurement operating costs
- Ensuring that revenue is adequate to support the office, and that finances are managed effectively
- Filling key positions with well-trained and motivated staff
- Maintaining effective working relationships with senior management and with clients

Senior management is responsible for assuring that these considerations are properly addressed and particularly for enforcing transparency and equity in the purchasing process.

Responsibilities in the procurement process

Effective procurement is a collaborative process between the procurement office, which manages many of the steps, and technical and policy committees, which should usually make the decisions about which medicines to buy, in what quantities, and from which suppliers. In a complex setting such as a procurement program at the national level, the following division of responsibilities may be appropriate.

Procurement office. The procurement office, which may be part of the government or independent, collates information on medicine needs, develops a proposed procurement list based on clients' requirements, manages the tendering process, manages and arranges supply contracts unless there is a separate tender board, and monitors performance of suppliers and of clients.

Staff of the procurement office should not have the sole deciding voice in determining which products are purchased and which suppliers receive contracts; these decisions should be made by committees that include representatives from other administrative sections or stakeholders, including client facilities. This separation of powers helps ensure broad ownership of the system and avoids conflicts of interest. If the procurement office is independently operated, it is important that its operations be supervised by a board of directors that includes senior health-policy makers.

Tender board. In many countries, tendering and contract negotiation are done according to law by a government tender board, which either reports to the finance ministry or is independent of any ministry. In such situations, the procurement office prepares the list of requirements, and the tender board may monitor the tender process. The prime task of the tender board is to make the award decision; in some cases, this will be an absolute decision, while in others, the tender board will make recommendations to health officials. Whichever system is followed, it is essential that the health system provide technical input into the contract award decision.

Medicine selection committee. Often the same as the formulary committee or pharmacy and therapeutics committee, the medicine selection committee should comprise knowledgeable practitioners and other health professionals who evaluate competing drug products in various therapeutic categories and select products that are most essential to the health system. A senior physician frequently chairs the committee, and a pharmacist generally serves as organizing secretary. The committee reviews requests for additions to the procurement list, compares the cost effectiveness of medicines on the list, and recommends which medicines to purchase, and when necessary, which medicines to delete. The committee also determines which therapeutic categories, if any, are suitable for open tender by therapeutic class. The committee needs access to current, unbiased drug information and members who can synthesize such information to make appropriate selection decisions.

Procurement/tender committee. Whether or not a government tender board is in charge of tendering, the health system should establish a procurement committee to make final decisions or to make the recommendations for such decisions to the tender board on medicine selection, procurement quantity, and supplier selection, and approve the exact specifications for product description, packaging and labeling, and quality assurance standards. The committee should base those decisions on recommendations from technical committees and subcommittees. It reviews information on suppliers and determines which should participate in tenders, if a restricted tender is used, and which suppliers should receive contracts, unless such decisions are made by a separate tender board. The procurement committee should include senior officials from the highest level of government served by the procurement system as well as officials from user facilities. For example, a federal government program that serves teaching hospitals and regional health systems might include two or three representatives of the ministry of health, two or three regional representatives, and one or two teaching hospital representatives.

In some countries, separate subcommittees develop product specifications and investigate suppliers' qualification for participation in tenders.

Procurement office staffing and management systems

The structure of the procurement office depends on the scope of the program, the availability of funds, and whether the office is managed as a government entity or as an independent agency.

Staffing requirements. In general, the procurement office needs a director, an assistant director, and experienced technical staff members, with at least one pharmacist or physician to provide sound technical input for the development and refinement of procurement lists.

Accounting and finance officers are needed to manage the accounts and in some systems manage payment to suppliers. Automated offices need data processors and at least one information technology professional. Also needed are one or more clerical managers, one or more secretaries or clerks, a receptionist or telephone operator, maintenance staff, and, in some systems, a driver and security staff.

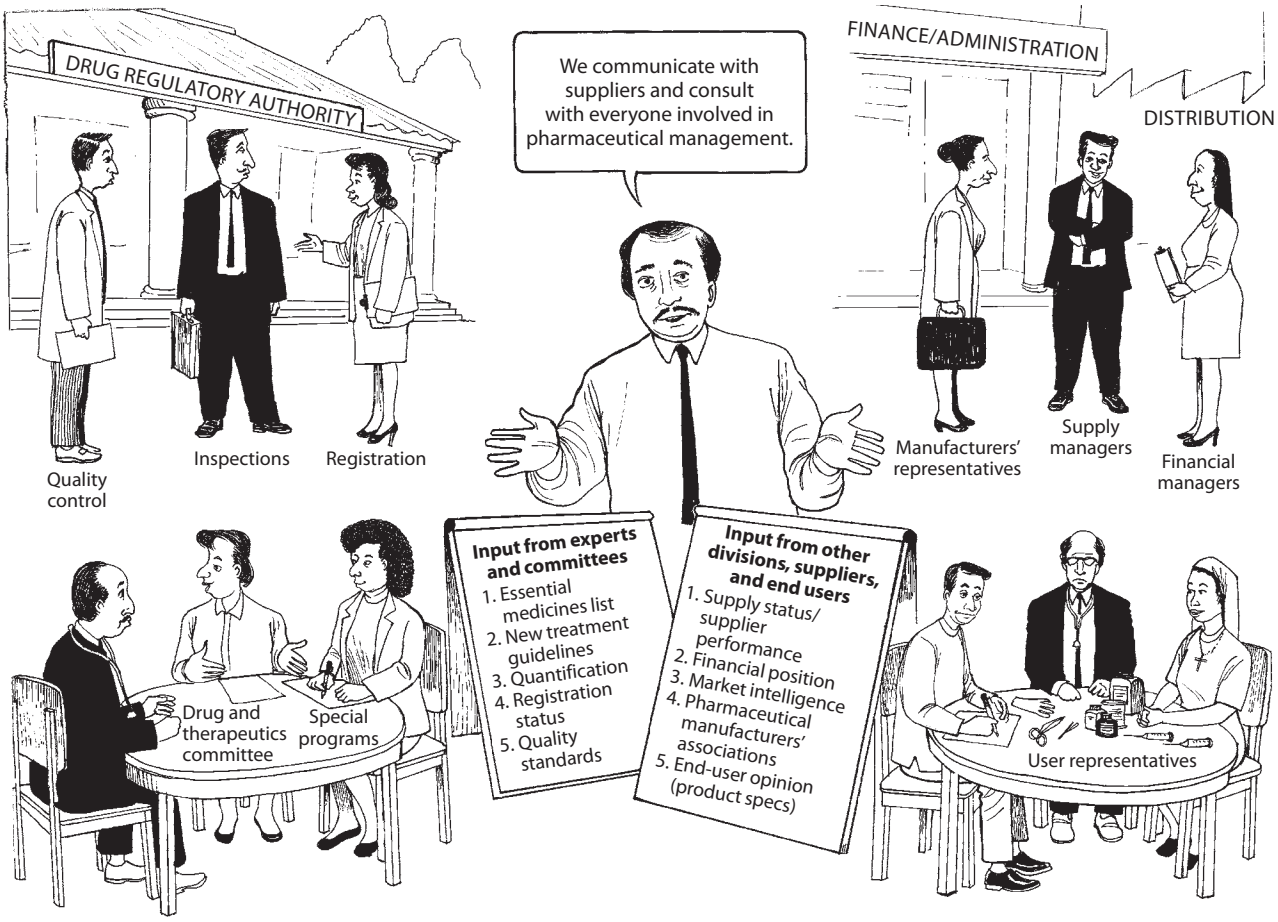
Staff in key procurement and distribution positions must be well trained and highly motivated, with the capability to manage the procurement process effectively. Unfortunately, in many countries, people are transferred just as they become competent in a position, and a new cycle of training and time lag between appointment and competence must begin again.

Salaries for procurement staff. When procurement office salaries are too low to support an individual or a family, or much lower than for equivalent work in the private sector, corrupt practices and neglect of duties are much more likely to occur. These kinds of problems increase funding requirements to replace the resulting theft and waste. Paying reasonable salaries in the first place and implementing tough controls is more cost-effective.

In some countries, restructuring the procurement office as an independent parastatal or privatized unit may be the only way to pay adequate salaries to staff.

Communications and market information. To succeed in the international market, procurement programs need two sorts of critical information: comparative price and availability data on products in the national and international pharmaceutical market and information about suppliers' capacity, reliability, and quality. Health system procurement agencies without access to price information or to the performance record of international suppliers operate in a vacuum and are essentially at the mercy of the marketplace.

Access to information depends on communications capacity. An Internet and e-mail connection and



GOOD COMMUNICATION IS ESSENTIAL TO THE PROCUREMENT PROCESS

external telephone line are essential in modern procurement, even if all procurement is done through local suppliers. For international procurement, direct access to an overseas line is mandatory. Countries have sources of comparative price information including the *International Drug Price Indicator Guide* (MSH, published annually), the annual source and price guide for HIV/AIDS medicines and commodities (WHO/UNICEF/UNAIDS/MSF 2005), the Global Fund's price and quality reporting tool (http://www.theglobalfund.org/en/procurement/pqr/), and other national and multicountry resources that WHO makes available on its website (http://www.who.int/medicines/areas/access/ecofin/en/index.html) and through its Procurement & Supply Management Toolbox (http://www.psmtoolbox.org). Chapter 21 discusses options for obtaining and evaluating information about pharmaceutical suppliers. A central repository of international information on worldwide supplier performance and tender pricing would be useful but has not yet proved feasible.

Tracking performance of the procurement system. A reliable management information system (MIS) is one of the most important elements in procurement. Lack of a functioning MIS or the inability to use it appropriately is a primary cause of program failure.

The MIS must be used to track all orders placed, the number and status of shipments and receipts, compliance with contract pricing, lead time of each order, payments made by the office or by group members, performance bond status, and the results of any investigations related to product quality.

The information system should also track the performance of health system units, number of orders placed, payments made, quantities actually purchased compared with estimates, purchases from all contract suppliers, and if possible, pharmaceutical purchases from noncontract suppliers. In all but the smallest procurement systems, the MIS should be computerized.

Computerized procurement information systems depend on appropriate software (Chapter 50). Key staff must be familiar with the software, and competent data entry personnel must be available.

Procurement manuals and technical assistance. Achieving and sustaining an efficiently functioning procurement

system are complex and demanding jobs. Using written policies and procedures that spell out how the procurement process should be managed and how the procurement system should operate is critical. A comprehensive procedures manual can be time-consuming to develop, but worthwhile if actively used to orient and manage staff.

The Global Fund to Fight AIDS, Tuberculosis and Malaria publishes policy guidelines for procurement through its program (Global Fund 2009). For purchasing through World Bank–financed loans, the World Bank's *Standard Bidding Documents for Procurement of Health Sector Goods* (World Bank 2004b) and *Procurement of Health Sector Goods Technical Note* (World Bank 2000) are essential references. A recently developed procurement system assessment tool, funded by the World Bank, includes transparency indicators in its evaluation (see Country Study 36-3).

When starting a new procurement system or revamping a poorly functioning system, outside technical assistance may help local managers in design and implementation. A number of organizations offer materials and technical support to help procure pharmaceuticals and commodities; for example, WHO has procurement assistance programs specifically for medicines and supplies related to HIV/AIDS, malaria, and tuberculosis (AIDS Medicines and Diagnostics Service, Roll Back Malaria's Commodity Services, and Global TB Drug Facility). WHO also provides other types of technical assistance on procurement issues in addition to its supplier prequalification program. The U.S. Agency for International Development funds several global and local programs that provide assistance to country-level pharmaceutical procurement programs. Other bilateral agencies, such as the U.K. Department for International Development, the Danish International Development Agency, and others, fund support to focus countries and regions, and major development banks and United Nations agencies such as UNICEF and the United Nations Development Programme provide procurement support in some countries (see the Glossary and References and Further Readings sections for more information).

18.7 Financial sustainability

Procurement programs cannot function effectively when funds are chronically inadequate. Traditionally, many countries have relied totally on the public budget to support pharmaceutical procurement, with medicines provided free to both inpatients and outpatients. In some countries, pharmaceutical purchases have consumed 20 to 40 percent of the total public health budget. The reality is that few countries have sufficient budget capability to purchase enough medicines to cover the needs of all patients, without supplementing the budget with some sort of cost recovery or donor support.

An epic occurrence in international health and development was the advent in the 2000s of global financing mechanisms such as the Global Fund, PEPFAR, and UNITAID, discussed in Chapter 14. These initiatives provide large-scale financing for countries to procure medicines and essential commodities, and in some cases, support global procurement mechanisms that make a limited range of commodities directly available to countries, such as the SCMS and Global Fund voluntary pooled procurement programs described earlier. Despite the increasing scope of these initiatives, financing issues still require the attention of health systems managers.

Sources of funds for pharmaceutical procurement

Primary sources of funds for pharmaceuticals include government financing, user fees, health insurance, community cofinancing, and donor financing. Chapter 11 describes these options in terms of their efficiency, equity, feasibility, and sustainability.

The most important considerations for procurement are regular access to and availability of funds and adequate access to foreign exchange. Government and donor funds are sometimes released irregularly throughout the financial year, and regulations often specify that funds must be spent in the year in which they are allocated or be returned to the treasury. Together, these factors may make it difficult to operate proper procurement systems and to obtain the best prices.

Strategies such as decentralized financial management and various types of revolving drug funds have been used to separate pharmaceutical procurement from the annual treasury cycle. This separation also often requires some form of cost recovery, which the decentralized mechanism manages.

Uncoupling the procurement cycle from the treasury cycle has substantial management advantages. Inventory management improves when medicines can be ordered when needed rather than at an arbitrary point in the government fiscal year. When suppliers know that orders will be placed promptly after tendering and that payment will be made according to contract terms, prices will be much more competitive.

Pharmaceutical financing issues that affect the procurement system are discussed in Chapters 9–14. These issues include the actual revenue potential of user-fee programs, equity aspects of user fees, management and accountability requirements for successful user-fee programs, the role of health insurance and other social financing mechanisms, the role of donor financing, and related issues. For donor financing, grants and loans should be clearly distinguished:

loans may be necessary to finance the start-up capital for a revolving drug fund or for a major emergency, but are an undesirable mechanism for financing the recurrent costs of supplying medicines.

Access to foreign currency exchange

Pharmaceutical procurement almost always requires the health system's largest outlay of foreign currency exchange. Shortage of foreign exchange can constrain international procurement and be a country's rationale for seeking donor support for pharmaceutical purchases. In situations where foreign exchange is constrained, procurement and pharmaceutical management systems should be as efficient as possible, so that they make the best use of local supply sources of products meeting established quality standards and obtain the best possible prices in international procurement. Sound documentation of actual needs and of economical use of funds may help justify increases in foreign currency exchange allocation from the ministry of finance or central bank. For example, in the Organisation of Eastern Caribbean States' Pharmaceutical Procurement Service, the Eastern Caribbean Central Bank handles the program's currency exchange from Eastern Caribbean dollars and pays suppliers in U.S. dollars at no charge to participating countries (Burnett 2003).

Reliable payment mechanism

As discussed earlier, sustained low pharmaceutical prices are possible only when a procurement program can guarantee prompt payment in full according to contract terms.

One example of sustainable financing is the revolving drug fund described in Country Study 18-2. However, revolving drug funds work only if the political will and financial capacity exist to replenish deposits in the fund each time purchases are made. Otherwise, the fund will soon vanish. Examples are numerous: one cautionary tale comes from Central America, where a European donor provided capital for revolving funds in several countries. Within a few years, all but one of the funds were totally decapitalized. That one country continued with the program for an additional year, but it experienced periodic problems with replenishing the account after purchases were made, resulting in delays in procurement and stockouts in health facilities; eventually the system ended.

Financial support for the procurement office

Procurement services may be part of the warehouse and distribution operation or be set up as a separate procurement office. In either case, salaries and operational costs of the procurement function must be covered. For typical public procurement systems, the only existing funding source for the procurement office is support through the government budget.

For pooled procurement programs that have a centralized procurement office that is not a formal government office, options may include—

- A periodic percentage payment to the office from group members, based on the invoice value of shipments
- A percentage payment from group members at the beginning of the procurement cycle, based on the projected value of the total procurement, or at the end of the cycle, based on the actual value of total shipments
- Payment from group members in the form of a flat annual fee, based on total expenses divided by the total number of areas and independent institutions served

The proper choice depends on the situation. The risk in tying a procurement office's reimbursement to the value of purchases by user facilities is the possible incentive for the procurement office to increase, rather than decrease, prices and total purchases. Therefore, if this approach is used, checks and balances must be put in place, such as using budget price volume instead of actual buy price or requiring that user representatives make all major procurement decisions. ■

Glossary

ABC value analysis: Method by which medicines are divided, according to their annual usage (unit cost times annual consumption), into Class A items (the 10 to 20 percent of items that account for 75 to 80 percent of the funds spent), Class B items (with intermediate usage rates), and Class C items (the vast majority of items with low individual usage, the total of which accounts for 5 to 10 percent of the funds spent). ABC analysis can be used to give priority to Class A items in procurement, inventory control, and port clearing.

Active pharmaceutical ingredient (API): That portion of a drug product that has therapeutic properties.

AIDS Medicines and Diagnostics Service (AMDS): A WHO-sponsored network to provide resources and technical assistance to countries buying pharmaceuticals and diagnostics for HIV/AIDS programs (http://www.who.int/hiv/amds/en).

Annual purchasing: A periodic inventory control system in which pharmaceutical requirements are determined and orders are placed once a year.

Back order: An order for a product that is currently out of stock. Back orders are filled when a new supply of the product becomes available.

Basic unit: The smallest unit in which a medicine can be conveniently dispensed or administered. It is used in quantification, reorder formulas, and comparison of prices of different-sized bottles or vials. Typical basic units are tablet or capsule, mL (for liquids), and g (for ointments and creams).

ASSESSMENT GUIDE

Procurement performance indicators

- Percentage by value of ministry of health (MOH) medicines purchased through a central procurement system
- Percentage of average international price paid for last regular procurement (indicator medicines)
- Percentage by value of MOH pharmaceutical purchases that are on the essential medicines list or national medicines formulary
- Percentage by value of MOH medicines purchased through competitive tender
- Percentage by value of medicines purchased from local manufacturers
- Average lead time for a sample of orders (calculated separately for all suppliers, local manufacturers, foreign suppliers)
- Average time for payment for a sample of orders (calculated separately for all suppliers, local manufacturers, foreign suppliers)
- Percentage of pharmaceuticals (batches) subjected to quality-control testing compared with target percentage to be tested
- Percentage of pharmaceuticals (batches) that failed quality-control testing

Procurement system procedures

- What type of system is used to supply medicines to public facilities (CMS, autonomous agency, direct delivery, primary distributor, private pharmacies)?
- What type(s) of purchasing models are used at each level of the supply system (annual, scheduled, or perpetual)?
- How are order and tender quantities determined at each level of the system?
- How are suppliers selected for tender or negotiation—does a formal qualification process exist?
- Is procurement done using generic names, brand names, or a mix?
- Are therapeutic equivalent medicines purchased through therapeutic subcategory tendering?
- How are lead times factored into ordering formulas and safety stock requirements?
- Are purchases limited to items on the formulary or essential medicines list?
- What constraints limit successful procurement in the public-sector pharmaceutical supply system?

Procurement system responsibilities

- Which agency or office is responsible for procurement of medicines and, if different, vaccines, contraceptives, diagnostics, and medical supplies?
- How are procurement responsibilities divided for medicine selection, needs estimation, tender management, and contract awards?
- Are written procedures for tenders and contract awards in place and regularly followed? Is the tender process transparent?
- What type of procurement management information system is used, and what kinds of reports are produced?
- How does the purchasing office obtain information on comparative prices and new supplier performance?
- What kinds of computers and computer applications are used to manage procurement?
- Is information available to carry out ABC, VEN, or total variable cost analyses?
- What procedures are used for monitoring supplier performance and enforcing procurement contracts?

Procurement finance

- What are the usual payment terms, payment lead times, and current debts owed to local and international suppliers?
- Does a problem exist with currency-exchange status in the public sector? If so, what impact does this situation have on pharmaceutical procurement?
- Are funds available as needed or is a fixed schedule used for the release of funds (and what approvals are needed)?
- Do cost recovery or drug revolving funds contribute significantly to procurement financing?
- To what degree is procurement financed by donors or by loans from development banks?

Batch: The quantity of a pharmaceutical produced in one production run.

Bid bond: A form of financial guarantee provided when a bid is submitted. The bond is forfeited if the successful bidder withdraws the offer or refuses to agree to the announced contract requirements.

Bulk purchasing: Procurement of pharmaceuticals in large quantities in order to obtain lower unit prices. Generally done in a bid system in which all medicines are identified by their generic (INN) name.

Call for offers: A publicized invitation to bid. Used in tender or bid purchasing. Includes product specifications, required delivery date, closing date for submitting offers, and other requirements of participation.

Certificate of manufacture: A document accompanying a commercial invoice that is presented to the buyer's bank—usually one of the requirements of a letter of credit—certifying that the products have been manufactured, are ready for shipment, and are in safekeeping.

CIF (cost, insurance, freight): When a seller quotes CIF, the costs of goods, marine insurance, and transportation to the named destination point are included.

Competitive negotiation: A procurement method by which the buyer approaches a small number of selected potential sellers and bargains with them directly to achieve specific price or service arrangements (used primarily in the private sector).

Compound: To mix together the ingredients of a prescription or pharmaceutical formula. Generally refers to a manual process performed for individual orders by a dispenser or pharmacist.

Consumption: The rate at which items are issued to clients or patients. This is also called demand (which is, in strict terms, the rate of requests or orders). Consumption is usually measured in terms of units consumed within a specific period.

Consumption-based estimate: Prediction of future pharmaceutical requirements on the basis of historical information on pharmaceutical consumption.

Direct procurement: The simplest but usually most expensive method of procurement, in which an item is purchased from a single supplier at its quoted price.

Disintegration: The breaking up of a tablet or capsule into granules or aggregates in an aqueous fluid.

Dissolution: The breaking down of fine particles into molecules or ions homogeneously dispersed in an aqueous fluid.

Estimated-quantity contract: A supply contract for a fixed period that stipulates an estimated total quantity, with the actual total quantity determined by orders placed as needed at the contract price during the contract period.

Excipient: An inert substance used to give a pharmaceutical preparation a suitable form or consistency.

Expiry date: The date appearing on a drug product and established by the manufacturer beyond which the manufacturer will not guarantee the potency, purity, uniformity, or bioavailability of the product.

External packaging: The case, crate, carton, or other container in which individual packages are placed.

FAS (free alongside ship): Used to indicate only the cost of transporting the goods to a ship are included by the seller. Carriage and freight are specifically excluded.

Financial guarantees: Deposits in the form of earnest money, bid bonds, performance bonds, or retention money required of suppliers to guarantee their participation once they have submitted bids or to ensure the complete fulfillment of contractual obligations by the supplier that wins the bid.

FOB (free on board): Used to indicate only the cost of transporting the goods to and on board a ship are included by the seller. Carriage and freight are specifically excluded.

Freight: The fee charged for carrying goods. The term is also applied to the items to be carried although the correct term for them is *cargo*.

GDF (Global Drug Facility): An organization that currently both supplies and acts as a procurement agent for anti-tuberculosis drugs for developing countries (http://www.stoptb.org/GDF/default.asp).

Global Fund to Fight AIDS, Tuberculosis and Malaria: An international, independent public-private partnership designed to attract and manage significant funding to finance the fight against AIDS, tuberculosis, and malaria (http://www.theglobalfund.org).

GMPs (good manufacturing practices): Performance standards for pharmaceutical manufacturers established by WHO and many national governments; they include criteria for personnel, facilities, equipment, materials, manufacturing operations, labeling, packaging, quality control, and, in most cases, stability testing.

GPP (good procurement practice): The internationally recognized concept of using best-practice principles in procurement, marked by openness and transparency.

Group purchasing: Purchasing done by one procurement office on behalf of a group of facilities, health systems, or countries. Group members agree to purchase certain medicines exclusively through the group.

Hidden costs: Costs in addition to the contract price that are not paid to the supplier but are real costs to the supply system. These include costs associated with poor quality, late deliveries, defaults on deliveries, short packing, and other factors.

Identity: Presence of the correct active ingredient in a drug product.

Immediate container (package): The individual jar, bottle, box, blister pack, or other container in which a single group of items is packed.

International procurement services: Organizations such as UNICEF, IDA Foundation, SCMS, and other groups that supply medicines on a nonprofit basis.

Inventory: The sum of all items held in stock.

Inventory-holding cost: Also known as *carrying cost*. The cost of holding one unit of an item in stock for a year. It may be expressed as a monetary amount or a percentage of purchase cost. This includes capital costs, costs associated with storage space, utilities, handling costs, losses due to waste and theft, and storehouse administrative costs. These costs may be 20 to 40 percent of the purchase price for a year.

Inventory value: The sum of the number of units of each item on hand or in storage in the system multiplied by the current unit price of each item.

IQC (Indefinite quantity contract): A contract that provides for an indefinite quantity, within stated limits, of specific supplies or services to be furnished during a fixed period with deliveries to be scheduled by placing orders with the contractor.

Issue unit: The quantity or size of each item counted in the stock records. For example, in some supply systems, the unit for tetracycline capsules might be one bottle of 100 capsules, and in others it might be one capsule. This is not necessarily the same as the basic unit or comparison unit, although they may be the same (see Chapter 50 for a discussion of units).

Item: A unique product for inventory purposes. In pharmaceutical supply, an important issue is whether generic equivalent items are treated as the same item or whether different brands of the same generic product are treated as different items. The item is sometimes called a stock-keeping unit (SKU), which is *not* the same as an *issue unit*.

Lead time: The time interval needed to complete the procurement cycle. It begins at the time the need for new stock is recognized and ends when that stock is received and available for issue.

Lead-time analysis: A systematic study of the components of lead time, aimed at discovering areas in which lead time can be reduced.

Line item: A product listed on an order or invoice. Each separate product on the document is one line item, no matter what quantity of the product is listed.

Make or buy: A management decision that involves the analysis of the cost and potential benefits of manufacturing a product rather than buying it on the open market.

Monopsony: A monopsony is a market with only one buyer. The buyer's-side analogy is a monopoly, in which there is only one seller in a market.

Open tender: The formal procedure by which quotations for the supply of pharmaceuticals under their generic names are invited from any local or international manufacturer or representative, subject to the terms and conditions specified in the tender invitation.

Opportunity cost of inventory: The cost of monies tied up in inventory. If average inventories increase, then capital invested in inventory increases proportionally. Since these funds invested in inventory could be used for other expenditures, they should be valued at current bank interest rates.

Order quantity: The amount of stock to be ordered (or that has already been ordered) via requisition or purchase order from a supplier or supply point.

Order status: The position of an order with respect to the specific tasks that must be performed for the order to be delivered to the buyer.

Payment terms: The conditions arranged between a buyer and a seller regarding the method of reimbursement. Letters of credit and commercial or deferred terms are the most common.

Performance bond: A form of financial guarantee that the supplier deposits when accepting the contract. This amount is forfeited if the supplier defaults on the contract.

Perpetual purchasing: A procurement model in which stock levels are reviewed continually, and orders are placed whenever stock levels fall below designated or calculated reorder points.

Pooled procurement: Another name for group purchasing.

Population-based estimate: Prediction of future pharmaceutical requirements based on the demographic composition of the population, disease patterns, and norms for treatment.

Port clearing: The process of locating items in port, obtaining the proper import documentation, paying the necessary fees, and inspecting the pharmaceuticals for damage during transit.

Potency: The extent to which a medicine contains the specified amount of the active ingredient.

Procurement: The process of acquiring supplies, including those obtained by purchase, donation, and manufacture.

Procurement period: The period of time between an order to a supplier and the next scheduled order.

Product file: A card or ledger file that records the technical specifications and performance of suppliers for each product.

Purchasing costs: All costs involved in placing and monitoring an order, including communication costs, the cost of preparing an order or tender and of subsequent negotiations, the staff time involved in routine checking of inventory levels, costs of receiving goods, any related special fees, and administrative costs. In practice, the cost of each order is estimated by dividing the total annual direct and indirect costs of the purchasing department by the number of orders placed in the year.

Purity: The extent to which medicines are free from potentially harmful contaminants, significant quantities of other medicines, bacteria, or other microorganisms.

Quality assurance: The management activities required to ensure that the medicine that reaches the patient is safe, effective, and acceptable to the patient.

Quality control: The testing of medicine samples against specific standards of quality.

Quantification: Estimation of the quantities of specific medicines needed. Financial requirements for purchasing the quantities are also calculated.

Restricted tender: Procurement procedure in which participation in bidding is limited to suppliers that meet certain prerequisites or have previously registered as suppliers.

Retention money: See **Performance bond.**

Roll Back Malaria Partnership's Commodity Services: A unit to support the procurement and supply management efforts for nets, insecticides, medicines, and diagnostics. The commodity service does not procure products itself, but it publishes market data, distributes forecast information, and fosters collaboration to address bottlenecks. (http://www.rollbackmalaria.org/psm/index.html)

Scheduled purchasing: Procurement model in which stock levels are reviewed periodically at set times during the year and orders are placed as necessary.

Secondary manufacture: The processing of medicinal substances, usually together with excipients, to produce a pharmaceutical dose form.

Shelf life: The length of time a material may be stored without affecting its usability, safety, purity, or potency.

Shortage cost: If emergency supplies are purchased to address a stockout, any increment in purchase price is a shortage cost. This cost is more difficult to quantify than holding cost but may still be significant. Loss of customers, decreased goodwill, and decreased sales are also real shortage costs if pharmaceuticals sales are involved.

Specifications: A precise description of an item to be procured, including any special requirements.

Stock: The items stored in a warehouse or facility (or health system). There are several types of stock:

- **Pipeline stock:** Stock that is in transit at various stages of the purchasing and distribution cycles.
- **Quarantine stock:** Stock that has been physically received in the storage facility but is held separately and not available for issue. There may be a need to confirm product quality or compliance with the contract, or the transfer to working stock might be delayed pending completion of necessary documents.
- **Safety stock:** The buffer or minimum stock that is kept on hand to protect against stockouts. If there is no safety stock, stockouts will occur when deliveries are delayed or when there is an unexpected increase in demand. In theory, the safety stock is separate from the working stock, but in practice there is no separation of the two, and safety stock sometimes must be issued.
- **Seasonal stock:** Stock that is acquired with the expectation that it will be needed to satisfy seasonal demand—for example, cough and cold medications in the winter. This stock is also part of the working stock once it is in the warehouse.

Vertical program stock: Stock that is not available on open request but is held for sole use by a vertical program, such as family planning or the Expanded Programme on Immunization (EPI). This stock may also be separated into working stock and safety stock.

Working stock: Stock that is on hand in the warehouse or storeroom and is shipped to requesting operating units. Working stock fluctuates as orders are filled and new stock arrives.

Other stock: Stock that is not usually issued but may be needed for purposes such as shipping or repackaging. May include items such as shipping tape, boxes, and labels.

Supplier: Any individual or company that agrees to provide medications, regardless of whether that party is the manufacturer.

Supplier file: A record kept for each supplier indicating when orders were placed, when they were received, what kind of service the supplier provided, and the quality of the product provided.

Supplier reliability: The past performance of a supplier in terms of medicine and packaging quality, timeliness of delivery, and level of service provided.

Supply Chain Management System (SCMS): A U.S. government initiative to procure and distribute HIV/AIDS-related pharmaceuticals and other commodities in countries supported by PEPFAR (www.pfscm.org).

Tendering: The procedure by which competing bids are entered for a particular contract.

Trade terms: A set of standard terms to describe the buyer's and seller's responsibilities in international trade—a list is found in Chapter 39.

VEN system: A system of setting priorities for purchasing pharmaceuticals and keeping stocks in which medicines are divided according to their health impact into vital, essential, and nonessential categories.

Wholesaler: A dealer who purchases supplies from a manufacturer and resells them to the ultimate buyers.

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