Supplementary Topics

Introduction

Throughout the *Procurement Capacity Toolkit*, many topics were introduced within specific modules that deserved additional writing. Rather than detract from the main topic of each module, the authors added this supplementary section, where specific topics are highlighted and discussed in further detail. Each of the topics in the supplementary section has some impact on the procurement process described in the body of the *Toolkit*. The supplementary topics were written as stand-alone pieces, intended to be read as individual documents.

Contents

A. Anticorruption Issues

B. e-Procurement

C. Letters of Credit

D. Payment Terms and Methods of Funds Remittance

E. Prequalification

F. Procurement Agents

G. Procurement Models: Centralized vs. Decentralized

H. Product Quality Assurance

I. Product Inspection and Testing

J. Recordkeeping

K. Regulatory Authorities

L. Standard Operating Procedures

M. World Bank Standard Bid Evaluation Form

A. Anticorruption Issues

Corruption undermines the economic and political foundations of a country and hinders the growth of trade and investment needed for development. In addition to negatively impacting economic development, corruption misallocates scarce resources, reduces resources for social services, dilutes public integrity, and violates human rights. This is especially true in developing countries where economic resources are limited and public institutions can be fragile. Corruption disproportionately impacts the poor and hinders efforts to achieve the United Nations Millennium Development Goals, which are aimed at measuring unprecedented global efforts to meet the needs of the world's poorest.

The consequences of corruption in the public health sector are especially critical, where the wastage of public resources can lead to reduced access to high-quality essential medicines. While it is impossible to determine the overall costs of corruption in the health sector worldwide, there is evidence that it amounts to tens of billions of dollars. It is estimated that annual earnings from the sale of counterfeit drugs in the United States alone amount to more than US$30 billion, which is only one component in the range of corrupt practices that exist.[*]

1. Forms of Corruption

The common forms of corruption as described by the World Bank are[†]:

- **Corrupt practice:** The offering, giving, receiving, or soliciting, directly or indirectly, anything of value to influence the actions of persons in the procurement process or contract execution.
- **Fraud:** The intentional, false representation or concealment of a material fact for the purpose of inducing another to act to his or her own detriment, thus benefiting the fraudulent party.
- **Collusion:** A scheme or arrangement between two or more bidders designed to establish prices at artificial or noncompetitive levels.

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[*] **Transparency International.** ***Global Corruption Report 2006—Part 2: The scale of the problem.*** **Page 25. Available at: http://www.transparency.org/publications/gcr/gcr_2006#download.**

[†] **World Bank.** ***Guidelines—Procurement Under IBRD [International Bank for Reconstruction and Development] Loans and IDA [Foundation] Credits.*** **Washington, DC: World Bank; 2004: 8–9. Available at: http://siteresources.worldbank.org/INTPROCUREMENT/Resources/Procurement-May-2004.pdf.**

- **Coercion:** Harming or threatening to harm, directly or indirectly, persons or their property; influence their participation in the procurement process; or affect the execution of a contract.

A personal conflict of interest can also be viewed as a form of corruption and can damage the reputation of public-sector procurement entities. Conflicts of interest arise when individuals with the responsibility to serve the public participate in activities that jeopardize their professional judgment, objectivity, and independence. They can also compromise the integrity and objectivity of the procurement process. Activities such as personal business ventures or associations generally serve personal interests or gains rather than the objectives of the individual's official duties. Common practices that can generate conflicts of interest include the distribution of free samples, gifts, and sponsored trips.

2. Vulnerability of the Health Care and Pharmaceutical Sector to Corruption

The health care and pharmaceutical sector is extremely vulnerable to corruption due to the considerable amount of money and commodities changing hands each year. Corruption can occur at different stages of the supply chain and take on different forms. For example, government officials may slow down the registration process in order to solicit payment from suppliers or suppliers may bribe officials to register medicines without the required information and data. Bribery can occur in the selection of medicines to be purchased, in the determination of a country's essential medicines list, or in the selection of which products are reimbursed through government social insurance programs. Favoritism can also occur during the process of selecting members for medicine registration boards.

As a result, large quantities of drugs and medical supplies can be lost along the distribution chain through theft or embezzlement by practices such as record falsification, dispensing drugs to ghost patients, and health care workers pocketing patients' payments.

For example, drug diversion throughout the supply chain in the public sector in developing countries can often exceed 15 percent.[‡] Two dangers in particular for HIV/AIDS drugs are the parallel drug trade and fake or counterfeit drugs. In parallel trading, drugs produced and sold at lower prices for the public-sector market are diverted and resold in the private

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[‡] **U4 Brief No. 4: *Anti-Corruption in the Health Sector—Preventing Drug Diversion Through Supply Chain Management*. Written for the U4 Anti-Corruption Resource Centre by Taryn Vian, Assistant Professor of International Health, Boston University School of Public Health. 2006. Available at: http://www.u4.no/document/u4-briefs/u4-brief-4-2006-health-drug-diversion.pdf.**

sector at higher prices. Often, pressures to rapidly scale up treatment programs in developing countries can require that funds be spent quickly, a known risk factor for corruption.

3. Causes of Corruption

Corruption principally occurs when social, judicial, political, and economic institutions operate in a system lacking checks and balances, and when policies do not enforce accountability, integrity, and transparency. Key determinants of a system susceptible to corruption as defined by the United Nations Development Programme are as follows:

- Poor transparency surrounding executive decisions combined with restricted public access to information.
- Elaborate regulatory systems allowing for discretionary decision-making.
- Weak systems of oversight and enforcement.
- A compensation structure within a state administration in which individuals receive meager salaries and have ample opportunity to engage in corruption.
- Low risk of exposure or probability of being caught, with few criminal consequences.
- Soft social norms allowing for a high tolerance for corrupt activities.
- The level of political stability or instability within a country.

Corruption in procurement and contracting within the health sector are similar to those that appear in other sectors, but some of the characteristics that increase the risk of corruption include:

- The complexity of the process to procure drugs and equipment.
- The number of parties involved in the procurement process, such as contractors, suppliers, medical institutions, administrators, regulators, and medical staff.
- Marketing practices by pharmaceutical companies that at times increase demand for products.
- Suppliers that use different prices for the same pharmaceutical product at different distribution tiers.
- Emergency situations that require rushed procurement decisions.

4. Measures to Address Corruption

The principal means for addressing corruption is to establish a procurement environment and system under which ethical procurement practices are fostered and supported. Key characteristics of an ethical, well-functioning public procurement system are transparency, open competition, economy and efficiency of the procurement process, fairness, and accountability toward the bidders. A clear, comprehensive legal and institutional framework is necessary to promote these characteristics and govern all aspects of the procurement process. At a minimum, procurement processes should provide for:

- Wide advertising of bidding opportunities and, if possible, using Internet postings or the World Bank and Inter-American Development Bank's Development Gateway Market (http://www.dgMarket.org) website.
- Maintenance of records related to the procurement process.
- Predisclosure of all criteria for contract award.
- Contract award based on objective criteria.
- Access to a bidder complaint review mechanism.
- Public disclosure of the results of the procurement process.

Other components and tools of an ethical procurement system include[§]:

- A clear institutional framework that separates those who carry out the procurement function from those who have oversight responsibilities.
- An independent agency that is responsible for overall procurement policy formulation and oversight regarding the proper application of procurement rules and regulations.
- Creation of conflict of interest policies and procedures, including identified areas of risk, a mechanism for registering personal interests and assets, and a policy to protect whistleblowers.
- Mechanisms for enforcement, including the right to audit and bidder complaint review processes.
- Monitoring systems for the procurement process that are transparent, accountable, and independent.

[§] **World Bank. Elements that Constitute a Well Functioning Public Procurement System. *Country Procurement Assessment Report* (Attachment 1). Available at: http://go.worldbank.org/37ANTSRFF0.**

- Reporting systems that are based on identified performance indicators and external audits to verify procurement accounting records.
- A well-trained procurement staff, technical assistance training for procurement officers, and training on existing procurement mechanisms.
- Established lists of reliable and well-performing suppliers.
- Use of price comparison tools, such as the *International Drug Price Indicator Guide* published by Management Sciences for Health.
- Use of tools such as the World Health Organization's manual for *Measuring Transparency in Medicines Registration, Selection, and Procurement: Four Country Assessment Studies* (2006). The manual covers the functions of registration, promotion, inspection, selection, and procurement, as well as instructions on collecting and calculating 51 indicators to monitor transparency.

Reducing poverty is a fundamental justification for fighting corruption. Corruption is a worldwide problem, but one that disproportionately affects the world's poor. Improving efficiency, accountability, and transparency in the procurement of goods and delivery and administration of public services are key elements to reducing corruption. Minimizing corruption requires an integrated and holistic approach that targets key institutional reforms, political and social accountability, and public acceptance of corruption.

Resources

The ***International Drug Price Indicator Guide***, published by Management Sciences for Health since 1986, provides a spectrum of prices from pharmaceutical suppliers and procurement agencies (such as the IDA Foundation) based on their current catalogs or price lists. It also contains prices obtained from international development organizations and government agencies.

Look up drug/contraceptive prices at http://erc.msh.org/mainpage.cfm?file=1.0.htm&module=DMP&language=English.

Alternatively, you can order the 2008 guide on CD-ROM at http://www.msh.org/resource-center/ebookstore/product.cfm?p=33.

Measuring Transparency in Medicines Registration, Selection, and Procurement: Four Country Assessment Studies, published by the World Health Organization in 2006, is available at http://www.who.int/medicines/areas/policy/goodgovernance/Transparency4CountryStudy.pdf.

U4 Anti-Corruption Resource Centre Website

The U4 Anti-Corruption Resource Centre assists donor practitioners in more effectively addressing corruption challenges through its development support. U4 serves eight development agencies: Norad (Norway), Department for International Development (United Kingdom), Canadian International Development Agency (Canada), GTZ (Germany), MinBuZa (the Netherlands), Swedish International Development Cooperation Agency (Sweden), Belgian Technical Cooperation (Belgium), and AusAID (Australia). The website home page can be found at http://www.u4.no/index.cfm.

The U4 website also has a focus on procurement of health-sector commodities and tools to fight corruption specifically in the health-sector area. Read ***Corruption in the Health Sector: Management of Medical Supplies*** at http://www.u4.no/themes/health/healthmedicalsupplies.cfm and ***Corruption in Public Procurement: Health Sector*** at http://www.u4.no/themes/procurement/procurementinhealth.cfm.

Transparency International

Transparency International (TI), a global civil society organization leading the fight against corruption, brings people together in a powerful worldwide coalition to end the devastating impact of corruption on men, women, and children around the world. TI's mission is to create change toward a world free of corruption. The TI website has many effective tools that can be used to curb corruption.

http://www.transparency.org/

Medicines Transparency Alliance

The Medicines Transparency Alliance is a multi-stakeholder alliance working to improve access to and affordability of medicines for the one-third of the world's population unable to access essential medicines due to high cost or local unavailability. The organization also has a focus on fighting corruption.

http://www.medicinestransparency.org/

World Bank

The World Bank is an international financial institution that provides leveraged loans to poorer countries for capital programs for the goal of reducing poverty. The Bank has identified corruption as among the greatest obstacles to economic and social development. It undermines development by distorting the rule of law and weakening the institutional

foundation on which economic growth depends. The World Bank's website on anticorruption provides information on addressing this problem.

http://web.worldbank.org/WBSITE/EXTERNAL/TOPICS/EXTPUBLICSECTORANDGOVERNANCE/EXTANTICORRUPTION/0,,contentMDK:21540659~menuPK:384461~pagePK:148956~piPK:216618~theSitePK:384455,00.html

Organisation for Economic Co-operation and Development

The Organisation for Economic Co-operation and Development (OECD) is an international organization of 30 countries that accepts the principles of representative democracy and free-market economy, seeks answers to common problems, identifies good practices, and coordinates domestic and international policies. The mandate of the OECD is broad, covering economic, environmental, and social issues. The OECD website on corruption provides information on improving good governance to fight corruption.

http://www.oecd.org/topic/0,3373,en_2649_37447_1_1_1_1_37447,00.html

B. e-Procurement

Electronic procurement, or e-procurement, refers to the automation of any part of the procurement process with electronic tools. e-Procurement solutions can range from a system that is fully integrated with purchasers' systems (e.g., linked with the warehouse management system), to partial automation of an organization's processes, to simply using a supplier's online tools. Many organizations are interested in automating some or all of their procurement activities to reap the benefit of reducing overall costs and the cycle time needed for the procurement process. Along with the potential benefits, there are additional costs and challenges facing any organization that plans to incorporate e-procurement.

It should be noted that a successful electronic system can only be built on existing sound procurement policies and practices. In other words, technology upgrades will not remedy a procurement system in need of process improvements.

1. e-Procurement Solutions

Organizations requiring a comprehensive e-procurement solution can purchase software packages from numerous vendors. The software generally includes features such as the ability to see and analyze organization-wide spending trends (spend visibility); online catalog management; automated procurement requisitions and approvals; electronic Requests for Proposals and bidding documents; electronic purchase order creation and submission; direct connections between buyers' and suppliers' online systems; warehouse management; and electronic invoicing, invoice matching, and payment.[**]

It is important to note that scanning documents and emailing them is not a comprehensive e-procurement solution. However, a movement toward electronic transactions is the first step and does save time and money. Similarly, an electronic system can assist with managing bidding documents, including distributing the documents to suppliers and capturing their responses. The electronic system would also become the document archive.

a. Potential Benefits

Many of the benefits associated with e-procurement relate to the reduction of resources needed to administer the procurement processes. This allows procurement staff to focus on

[**] **Australian Government Information Management Office. *Strategic Guide to e-Procurement*. 2006. Available at: http://www.finance.gov.au/Publications/strategic-guide-to-e-procurement/index.html.**

procurement strategy rather than the transactions. Some of the other potential benefits of e-procurement are:

- Reduced manual entry and manipulation of orders and invoices, which decreases errors.
- Decreased or eliminated paperwork.
- Reduced time needed to source products and suppliers.
- Reduced costs of advertising, printing, and mailing Requests for Proposals.
- Comprehensive audit trail and document archives.
- More consistent and transparent processes that decrease opportunities for corruption.
- Enhanced reporting capabilities that can be used to better monitor business activities and compliance with procurement policies.
- An improved invoice payment process that is faster and more accurate than manual processes.
- A prompt invoice payment process that can be useful for negotiating better terms or prices with suppliers.

b. Potential Challenges

As with the implementation of any new system, there are challenges an organization may need to address. The potential challenges associated with e-procurement are:

- Conducting good procurement practices on which to build the e-procurement system.
- Obtaining interdepartmental coordination with all departments impacted by e-procurement.
- Managing change throughout implementation to keep stakeholders aware of the new systems and processes.
- Potential implementation failure of e-procurement software and systems.
- Developing a realistic project scope and budget.
- Obtaining political will to transform existing government functions.
- Accessing adequate capacity to design and implement solutions.

- Adequately addressing privacy protection components of the e-procurement system.
- Providing security to the e-procurement sites from attack and misuse. This is important because security breaches can shatter public trust in procurement.
- Obtaining sufficient resources, people, and money to implement the e-procurement system.

2. e-Procurement Considerations

a. Costs

The cost of e-procurement software can be substantial and may be prohibitively expensive for smaller organizations and much of the public sector. Organizations must consider not only the price of the software itself but other costs associated with the system and its implementation. Those additional costs include networking infrastructure, information technology hardware and software, application design, development and implementation, training, and maintenance of equipment. There is also the time required for employees to learn the new system.

Most e-procurement activities in a government sector will need to be made available offline as well as online. While there can be savings even in this mode, the need to have offline and online operations in the initial phase will mean some additional costs.

b. Organizational Considerations

Given the costs, an organization should begin with analysis of current systems to determine if the benefits of e-procurement will be worth the investment. The first step is to perform a spend analysis. The spend analysis should identify the goods being purchased (spend categories), from which suppliers, and the value and number of transactions over a 12-month period. The data can then be assessed to identify spend categories that will yield the greatest benefit from automation. Some spend categories are more suited to e-procurement solutions than others. Similarly, e-procurement can offer savings on frequently purchased goods or services by reducing the transactional burden.

An upgrade to automated systems is not simply about technology, but also about the people responsible for using the technology. Organization-wide changes can have a dramatic impact on staff, and a plan for managing those changes must be carefully considered and implemented. Implementers should also be aware that e-procurement systems will have an impact that reaches beyond the procurement unit. For instance, the finance, accounting,

reproductive health, and legal departments may all be affected. Therefore, it is necessary to include them in the planning and adoption of any e-procurement solution. Buy-in and participation from the affected units and support from management will help to create a positive outcome.

It is not recommended that an organization attempt to automate all of its procurement processes at once. Organizations that cannot afford extensive e-procurement software can consider upgrading parts of their procurement system. A partial upgrade should still yield results.

c. Supplier Considerations

Any e-procurement strategy must take the suppliers' interaction with the system into account. Even with a procurement that is well suited to automation, the supplier might also need to be electronically enabled. Supplier willingness and ability to adopt e-procurement tools are crucial to successful implementation. Remember that suppliers will also have costs associated with e-procurement and may only be interested in a new system if it will provide a commercial benefit to them. Suppliers that can expect an increase in order volume will be more likely to engage in upgrades. Even if a supplier is not able to fully integrate with an e-procurement system, it may be capable and interested in using widely available tools such as email and spreadsheets. e-Procurement readiness can be included as part of future bid evaluations.

3. e-Procurement in the Public Sector

The use of e-procurement in the public sector can offer substantial benefits. However, the high costs and lack of a one-size-fits-all solution can be overwhelming. Therefore, careful consideration and planning must precede the adoption of any new tools. This should not deter an organization from seeking out the potential of an e-procurement system. Evaluations conducted by independent agencies of some government e-procurement projects indicate that costs of accessing services by citizens have been reduced, corruption has lessened, and government tax revenues have grown.[††] Experience shows that e-procurement in government can be developed in stages, with projects suitable for different levels of technology—in essence, beginning with a hybrid of automated and manual processes. Best practice e-procurement countries are Brazil, Chile, India, Romania, South

[††] **World Bank.** ***Introduction to e-Government: Overview of Key Concepts*****. Available at: http://web.worldbank.org/WBSITE/EXTERNAL/TOPICS/EXTINFORMATIONANDCOMMUNICATIONANDTECHNOLOGIES/EXTEGOVERNMENT/0,,contentMDK:20694364~pagePK:210058~piPK:210062~theSitePK:702586,00.html.**

Korea, and Sri Lanka. The case study in Section 4 below, on initiating e-procurement in Andra Pradesh, India, illustrates some of the challenges found in implementing an e-procurement system, as well as the benefits derived from it.

4. Assistance With e-Procurement in the Public Sector

The World Bank, under loan agreements, provides assistance to client countries in terms of e-procurement initiation, design, and implementation. It should be noted that the World Bank uses the term e-Government, which is synonymous with e-procurement. Its role can include financing e-Government projects and components; supporting e-Government approaches through policy advice, strategy formulation, and operational support; establishing a forum for knowledge-sharing on e-Government, including hosting video conferences; helping clients to create the necessary infrastructure for e-Government; providing technical assistance; and promoting the use of information technology in public-sector reforms.

The World Bank assisted the government of Bangladesh with an e-Government procurement readiness assessment, which was conducted in March 2006. The readiness assessment involved about 20 public- and private-sector organizations related to public procurement. The key components of the readiness assessment were government leadership, infrastructure and web services, human resources planning, standards, planning and management, private-sector integration, policy, systems, and legislation and regulation. The high-level result of the readiness assessment showed little to some evidence that the key components (listed above) were in place to support e-Government procurement.[‡‡] In general, the assessment emphasized the importance of assessing the overall system prior to implementation.

The Mexican government has also taken steps toward e-procurement by providing competitive procurement opportunities in 33 of its local governments through its Compranet service. Additionally, the Compranet service offers several online services for contractors and suppliers, enabling them to search for information on their contracts and payments.[§§]

[‡‡] **Government of the People's Republic of Bangladesh.** ***Electronic Government Procurement Readiness Assessment*****. 2006. Available at: http://www.cptu.gov.bd/EProcurement.aspx.**

[§§] **World Bank.** ***Introduction to e-Government: Overview of Key Concepts*****. Available at: http://web.worldbank.org/WBSITE/EXTERNAL/TOPICS/EXTINFORMATIONANDCOMMUNICATIONANDTECHNOLOGIES/EXTEGOVERNMENT/0,,contentMDK:20694364~pagePK:210058~piPK:210062~theSitePK:702586,00.html.**

In addition to the World Bank, another resource for assistance with e-procurement is the Asian Development Bank (ADB) (http://www.adb.org), operating in Asia and the Pacific region. The ADB is working with the Philippine government to improve the transparency and efficiency of procurement by continuing to strengthen the e-procurement system and implement it throughout other aspects of the government. The World Bank teams with ADB on these projects.

e-Procurement systems offer many benefits to procurement organizations and provide transactional cost savings over time. The implementation of an e-procurement system is dependent on adequate resources, both personnel and budgetary. It is important to take the time to consider all factors before making a final decision to transition to e-procurement. Seeking out assistance from organizations such as the World Bank can ease the transition and help to ensure successful implementation.

Case Study: e-Procurement in Andhra Pradesh India[***]

Background

In 2000, the Government of Andra Pradesh (GoAP), India, chose to introduce an e-procurement platform for procurement of goods, works, and services. Prior to that, the GoAP had been using a manual bidding system that required a lengthy process of internal authorizations and multiple visits by suppliers to departments, and created large volumes of paper-based statements and evaluations.

Problems of Manual Bidding

The manual bidding system suffered from the following problems:

1. Discrimination and delay by government departments in the release of bidding documents to suppliers.
2. Cartel formation by participating bidders to suppress competition.
3. Physical threats by factions against genuine bidders to prevent them from submitting bids.

[***] Case Study authors: K. Bikshapathi, Project Manager, e-Procurement; P. Ramarajo, Chief Engineer, Government of Andra Pradesh, Immigration Department; and Prof. Subhash Bhatnagar, Indian Institute of Management, Ahmedabad, India. March 2006.

4. Bidding document boxes were placed at multiple locations to counter the threats of contractor cartels, but this created an additional management and transport burden for government officials.
5. Bidding document files were tampered with or lost as they were physically transported through the administrative hierarchy.
6. Delays in finalizing bidding documents due to red tape, lack of transparency, and manual movement of bidding document files through the administrative hierarchy.
7. Exposure of department personnel to interfacing with bidders at every stage of the review and approval process, which can lead to subjectivity, favoritism, and other undesirable practices.
8. Lack of transparency resulting from government departments tightly controlling and closely guarding information, creating a lack of trust in the system by bidders, the media, and citizens.

A GoAP subcommittee on bidding reforms proposed creation of an e-procurement platform to address these challenges. The recommendation was based on the principle that automation of the procurement transactions would reduce human error, enhance the integrity of data, bring transparency to government procurements, and facilitate process standardization. The GoAP e-procurement process was designed to avoid supplier and buyer interaction during the pre- and post-bid processes. The procurement process and forms used by different departments were standardized, and to bring transparency to the e-procurement process, bidding documents containing all essential information and details were hosted on the website.

Challenges in Implementing e-Procurement

1. Selecting a sustainable business model with an appropriate implementation strategy: The GoAP decided on a public-private partnership model in which the private partner provided technology expertise and upfront investment while recovering costs through charges to user departments for completed transactions.
2. Ensuring interdepartmental coordination: A high-level steering committee comprised of heads of all the participating departments was formed to promote coordination.
3. Managing the change process: Implementation of e-procurement required adopting new ways of doing business for different stakeholders. Supporting this change process was achieved through establishing and monitoring procurement targets for each department, identifying project champions within each department to support

implementation, and conducting training workshops to effectively communicate the objectives and benefits of e-procurement.

4. Resolving security and authentication issues: Committed project teams were established to support security features.

Benefits and Cost Savings From Implementing e-Procurement

1. Bid cycle times were reduced: Prior to e-procurement, government departments took 90 to 135 days to finalize high-value bids. At the end of the second year of e-procurement, bid cycle times had been reduced to an average of 35 days.
2. Opportunities for corruption were reduced: Supplier and department interaction during pre- and post-bid processes was minimized. The automatic bid evaluation process reduced subjectivity in bid evaluation and helped to curb opportunities for corrupt practices to a significant extent and increased the accountability of procurement officials.
3. Cost savings were achieved: Bids processed during the first year of e-procurement yielded quotations that were 16 percent less than comparable quotations from the previous year of manual bidding. e-Procurement also encouraged competition by increased participation. Supplier participation increased from an average of 3 per bid in manual bidding to 4.5 in e-procurement. Departments recognized cost savings, with an average reduction of 20 percent in procurement transaction costs in 2003–2004 and 12 percent in 2004–2005.
4. Transparency improved: The use of automated bid evaluation through smart forms and parameterized qualification criteria improved transparency, reduced subjectivity in the bid award process, and reduced corruption.

Key Outcomes

1. Support of political leadership and formation of a high-powered steering committee.
2. A participative design process that included workshops attended by all key stakeholders.
3. A single mode of bid submission established through the e-procurement platform.
4. A sustainable model selected that is rational and affordable for the government and its implementing partners.
5. Committed project teams that support help desk and security features.

Resources

e-Procurement in Government of Andhra Pradesh, India (2006)

This is a case study of the implementation of e-procurement in the government in Andhra Pradesh, India, beginning in 2002. The reason for the implementation, challenges, and benefits are outlined in the document, found on the World Bank website.

http://web.worldbank.org/WBSITE/EXTERNAL/TOPICS/EXTINFORMATIONANDCOMMUNICATIONANDTECHNOLOGIES/EXTEGOVERNMENT/0,,contentMDK:20870206~menuPK:702592~pagePK:148956~piPK:216618~theSitePK:702586,00.html

e-Procurement Assessment Document, Bangladesh

This report details the findings, conclusions, and recommendations that arose from the *e-Government Procurement Readiness Assessment Report 2006* in Bangladesh. It serves as an example of the thorough assessment needed before launching an e-procurement system. The project was part of a wider project, the Economic Management Technical Assistance Project H107-BD, funded by the World Bank and the government of Bangladesh.

http://www.cptu.gov.bd/EProcurement.aspx (downloadable at the bottom of the website)

How To…Quantify and Realise the Benefits from e-Purchasing (United Kingdom Improvement and Development Agency, 2004)

This document describes e-procurement and its challenges and benefits.

http://www.idea.gov.uk/idk/aio/70858

Strategic Guide to e-Procurement (Australian Government, 2006)

This document provides guidance to agencies in developing e-procurement options, understanding business cases, and developing e-procurement plans that suit their needs and the needs of their suppliers.

http://www.finance.gov.au/Publications/strategic-guide-to-e-procurement/index.html

Toolkit: Implementing e-Government—Being Ready (New South Wales Government, 2001)

This is a practical guidebook to developing an e-government strategy for New South Wales government agencies. Topics include leadership and governance, funding, human resources capacity, legal frameworks, customer readiness and accessibility, privacy, technology information management, and security.

http://www.audit.nsw.gov.au/publications/better_practice/2001/e_gov_bpg_sept_01.pdf

World Bank e-Government Website

This site is intended as a knowledge repository of e-Government-related information and best practices and case studies. e-Government refers to the use of information and communications technologies to improve the efficiency, effectiveness, transparency, and accountability of government.

http://www.worldbank.org/egov/

C. Letters of Credit

Letters of credit (L/Cs) have been used for centuries as a way to safely move money around the world. In its contemporary form, the L/C permits a commercial bank to act as a trusted intermediary between buyer (referred to as the "applicant" in L/C transactions) and seller (referred to as the "beneficiary" in L/C transactions), guaranteeing that the seller will receive payment when it performs as required, and guaranteeing that the buyer's funds will not be paid out if the seller does not perform as required. Essentially, the bank enters into a contract with the seller in which it becomes responsible for the payment.

For purchasers, the L/C is an opportunity to enforce product quality and delivery requirements by linking proof of compliance to payment. This proof may take the form of quality assurance documents, inspection or testing certificates, or an authorization for shipment signed by the buyer's representative based on acceptable inspection or testing results.

A wider range of prospective suppliers is likely to be interested in doing business with developing economies with the use of an L/C, which can increase competition and potentially lower prices. The L/C can also take the place of advance payments, allowing an organization to retain control of its funds and even earn interest on them until the goods are shipped.

1. Letter of Credit Rules and Guidelines

Since 1933, the International Chamber of Commerce (ICC) has published universally accepted standards of L/C practice for bankers in its *Uniform Customs and Practice for Documentary Credits* (UCP).

The UCP defines rights and obligations of the various parties in an L/C transaction. These are recommended standards and not legally binding, however; therefore, any given L/C is subject to these standards only to the extent indicated in the L/C itself. So while L/Cs do not necessarily have to comply completely with the UCP, most banks will not issue L/Cs that do not generally conform to UPC standards.

Over the years, periodic revisions of the UCP have incorporated new developments and practices in world trade. The sixth and most recent version is *UCP 600* (published in 2007). The *eUCP* supplement published in 2002 provides specific guidance on electronic documents and communications. In addition, the ICC published *International Standard Banking Practice* in

2002, which is a resource for bankers regarding the examination of documents presented under documentary credits.

The publications mentioned above are highly recommended to readers who need more than high-level information about L/Cs.

2. Letter of Credit Variations

The L/C has a number of variations: it may be revocable or irrevocable, confirmed or unconfirmed, transferable or nontransferable, or it may be standby or commercial.

Two main variations of the L/C used in international trade are relevant for most reproductive health (RH) purchasers: the irrevocable L/C and the confirmed irrevocable L/C.

a. Irrevocable Letter of Credit

An irrevocable commercial L/C is a banking instrument that guarantees payment to the beneficiary (seller) when it has complied with the terms of the L/C. Usually, these terms include shipment of contracted goods, conformity with specified requirements, and presentation of specified documentary evidence to the bank proving compliance. Banks deal only in documents, rather than intentions. Therefore, they allow no discrepancies between the exact and precise requirements stated in the L/C and the documents presented by the beneficiary, unless expressly approved by the applicant (buyer).

b. Confirmed Irrevocable Letter of Credit

A confirmed irrevocable L/C is a double assurance of payment: the issuing bank makes a legally binding promise to pay a beneficiary, and a second bank (the confirming bank) adds its own legally binding guarantee to pay if the issuing bank defaults.

When L/Cs are issued through small, local banks, sellers often require the confirmation of a major international bank because they want to be completely assured of reliability. In other cases, the seller simply wants payment to be guaranteed by a bank located in its own country.

For RH programs in developing economies, it is important to use a bank for opening an L/C that has an official correspondent relationship with at least one major international bank so that appropriate confirmations are possible.

3. Payment Types

All credits must clearly state whether they are available by "sight payment" or by "deferred payment," and they must indicate for the bank authorized to pay to incur a deferred payment undertaking, to accept drafts, and/or to negotiate.

When the beneficiary (seller) presents the stipulated documents indicating that the terms and conditions of the credit are complied with:

- **Sight payment** requires that the nominated (authorized) bank pay the beneficiary upon presentation of a "sight draft."
- **Deferred payment** requires that the nominated bank pay the beneficiary on the maturity dates determined in accordance with the credit.

RH purchasers need to be aware of sight payment and deferred payment options when drafting contracts, as well as when opening L/Cs, because these options relate to *how* the seller will be paid. "Acceptance" and "negotiation" relate to *where* the seller will be paid. They are not usually addressed in an underlying contract between the buyer and seller, but come into play when the L/C is established.

- **Acceptance** refers to the acceptance of drafts drawn by the beneficiary on the issuing bank (and to pay them at maturity).
- **Negotiation** refers to payment without recourse—for example, the giving of value for drafts and/or documentation by the bank authorized to negotiate. Mere examination of the documents without giving of value does not constitute a negotiation.

4. Contractual Relationships

There are at least three separate contracts in operation under an L/C arrangement. As the reader may have realized by now, each contract is completely independent of the others. The contracts include:

- The sales contract between the buyer and the seller.
- The reimbursing agreement between the applicant (buyer) and the issuing bank (the bank that issues the L/C)—normally a deposit or set-aside of the applicant's (buyer's) funds in its own bank against the time the beneficiary (seller) fully complies with the requirements of the L/C and thus gains access to the payment.
- The L/C between the issuing bank and the beneficiary (seller).

- If the L/C is "confirmed" by another bank, then the confirming bank undertakes its own contractual arrangement with the seller (beneficiary), in addition to that of the issuing bank.

a. Role of an Advising Bank

An advising bank simply provides information with no contractual undertaking; however, in practice, the advising bank may also be the confirming bank.

5. Opening a Letter of Credit

The buyer (applicant) applies to its commercial bank to issue an L/C in favor of a seller (beneficiary). Banks usually provide standard application forms to their customers. These vary from place to place, but regardless of the form required, the applicant must describe the goods and spell out exact terms of the agreement, such as:

- How much is to be paid.
- What form of currency the agreement requires.
- Time limits for the shipment and presentation of the documents for payment.
- What documents must be presented in order to allow the bank to pay.

It is up to the applicant (buyer) to be explicit about these requirements. Words and phrases such as "promptly," "immediately," and "as soon as possible" should not be used in any context. Reference to an underlying contract between the buyer and the seller is not useful because the issuing bank has no rights, commitments, or interest in that contract; it is only concerned with and bound by the contract between itself and its customer.

The applicant always bears the risk of any ambiguity contained in its instructions to the bank, so it is very important for RH purchasers to ensure that their applications are clear, complete, and free of excessive detail that could lead to confusion or misunderstanding.

In some situations, the RH purchaser will be required to route its requests for opening L/Cs through another administrative unit—for example, a finance unit. It is not enough to simply transmit a copy of a contract to an intermediary unit (although that might be required as well); the RH purchaser should produce a separate document describing the goods, specifying how much, on what terms, and in which currencies payment is to be made, and indicating time limits for shipment. Most importantly, the RH purchaser must state specifically what documents are to be required for payment and by whom they should be produced. This is critical in the case of preshipment inspection reports and other tools for

assuring the quality and safety of the product, as it is very unlikely that another unit—such as a finance unit—would accurately identify every pertinent requirement from a lengthy contract.

If an L/C contains conditions without stating the document(s) to be presented in compliance therewith, the bank will deem such conditions as not stated and will disregard them.

a. Language

Under international standard banking practice, documents issued by the seller (beneficiary) will be in the language of the credit. However, banks may limit the number of acceptable languages as a condition of issuing the credit.

b. Collateral

In most cases, the applicant (buyer) will be required to deposit funds or assign already deposited funds equal to the expected payment. This is called "collateralizing" the L/C. These funds may not be used for other purposes, but the buyer (applicant) earns interest, or other benefit, on the deposit until the L/C is paid.

Role of a development bank or funder

In some cases, the RH program will be purchasing goods with funds provided by a development loan or credit, or another form of financial assistance. One of the ways funds can be made available for specific purchases is by the funder collateralizing an L/C. Alternately, it may arrange a payment guarantee, such as those executed occasionally by the World Bank. Usually such an arrangement is spelled out in an agreement between the funder and the recipient—essentially a contractual undertaking—made prior to initiation of any procurement activity.

c. Form

The issuing bank advises the seller (beneficiary) that the credit is open in its favor. The letter in which the issuing bank provides this advice is literally the "letter of credit"; it specifies the terms and conditions under which the credit operates. A copy is sent to the buyer (applicant). These documents and copies may be in an electronic format or in hard copy. In either case, the buyer (applicant) must check immediately to make sure the L/C reflects its instructions. If there are errors in the document prepared by the bank, a no-cost amendment can be requested. The seller (beneficiary) must communicate to the bank its acceptance of any amendment.

Amendments can also be requested either by the applicant (buyer) or the beneficiary (seller) to accommodate changing conditions, provided that the changes are acceptable to both parties. For instance, a delivery date may need to be amended based on an agreement between the seller and the buyer.

d. Cost

Banks charge a percentage of the value of the goods for opening an L/C. This charge is normally paid by the applicant (buyer). Banks levy additional fees for amendments, payments, and draw-downs. The L/C should stipulate whether the beneficiary or the applicant is responsible for paying these additional fees. Fees for opening an L/C will amount to at least several hundred dollars. Every bank is different, so the applicant should obtain this information at the initial contact. A typical fee ranges from 0.5 to 1.0 percent of the face value of the L/C. Fees may accrue for such items as:

- Issuance.
- Pre-advice.
- Advice.
- Amendments.
- Extensions.
- Confirmation.
- Documentary examination.
- Payment.
- Negotiation.
- Acceptance.
- Reimbursement.
- Collection without examination.
- Transfer.
- Assignment of proceeds.
- SWIFT.[†††]

[†††] **SWIFT stands for Society for Worldwide Interbrain Financial Telecommunication. It is a computer-based, standardized message-writing system that connects worldwide participating banks, primarily for the purpose of communicating payment information. It is used extensively in L/C operations.**

- Handling.
- Courier.
- Discrepancy.
- Cancellation.
- Discounting.

6. Settlement: Paying the Seller (Beneficiary)

In order to receive payment, the seller (beneficiary) submits documents specified in the L/C to the paying bank as proof that it has performed as required. These documents may include:

- Commercial invoices.
- Insurance certificates.
- Transport documents (such as the original bill of lading or air waybill).
- Certificates of Origin.
- Inspection certificates (e.g., Clean Reports of Findings).
- Authorizations for shipment.
- Other certificates and certifications (e.g., Certificates of Analysis).

The first three items are required. The last four items are optional and are often used by the purchaser as tools to enforce contract provisions.

The issuing bank, confirming bank (if any), or a nominated bank acting on their behalves, each have a reasonable time—not to exceed 7 banking days (5 banking days under *UCP 600*) following the day of receipt of the documents—to examine the documents, determine whether to accept or refuse them, and to inform the party from which the documents were received. If there are discrepancies in the documents—that is, if they are not precisely as required—the bank may contact the applicant (buyer) and ask if it wishes to waive a particular discrepancy, which may be no more than a misspelled word. If there are no discrepancies in the documents, the bank issues payment.

Resources

International Chamber of Commerce Business Bookstore

The ICC Business Bookstore contains key UCP documents, including *UCP 500*, *UCP 600*, and supplementary topics.

http://www.iccbooks.com/Product/intbanking.aspx

International Standard Banking Practice for the Examination of Documents Under Documentary Credits, 2007 Revision for UCP 600 (ICC)

An update of the successful ICC Publication No. 645, this publication reflects international standard banking practice for all parties to a documentary credit under *UCP 600*.

http://www.iccbooks.com/Product/ProductInfo.aspx?id=485&cid=116

All About UCP 600: Uniform Customs and Practice for Documentary Credits (Rupnarayan Bose, 2008)

All About UCP 600 provides a detailed analysis of the articles of *UCP 600*. The book meticulously traces the process of the evolution of the UCP from *UCP 500* to *UCP 600*, and faithfully reconstructs the significant stages up to its final transformation. It addresses the major considerations that eventually created the UCP as we know it today. It also highlights the changes introduced by the ICC and underscores their implications for trade and industry.

Available for purchase at: http://www.infibeam.com/Books/info/rupnarayan-bose/all-about-ucp-600-uniform-customs-practice-documentary/9780230636736.html

D. Payment Terms and Methods of Funds Remittance

Payment terms and methods of funds remittance are important aspects of every procurement process because they establish risks and costs for each party to the contract. Both buyers and sellers want the most financially advantageous terms with the least risk to themselves. The challenge is that the least risk to the buyer usually means the most risk to the seller and vice versa.

The United States Department of Commerce International Trade Administration depicts this conflict in an interesting way[###]:

> International trade presents a spectrum of risk, causing uncertainty over the timing of payments between the seller (exporter) and buyer (importer). To exporters, any sale is a gift until payment is received; therefore, the exporter wants payment as soon as possible, preferably as soon as an order is placed or before the goods are sent to the importer. To importers, any payment is a donation until the goods are received; therefore, the importer wants to receive the goods as soon as possible, but to delay payment as long as possible.

The method of procurement determines who decides on *payment terms* and, to a lesser extent, *methods of funds remittance*:

- If an organization uses a competitive bidding process, the decision is made by the procuring entity (the buyer) when it prepares bidding documents for circulation to potential suppliers. In responding with a bid, each prospective supplier (seller) agrees to the terms set out in the bidding documents. Thus, the buyer determines payment terms and does so far in advance of awarding a contract.
- If an organization uses a less structured approach to procurement (such as a Request for Quotation), the prospective supplier (seller) normally proposes payment terms. These terms as well as other aspects of the future contract are negotiated between buyer and seller. Thus, both parties determine the terms prior to concluding a contract.

[###] **United States Department of Commerce International Trade Association. *Trade Finance Guide: A Quick Reference for US Exporters*. Washington, DC: United States Department of Commerce; 2007. Available at: http://trade.gov/media/publications/pdf/trade_finance_guide2007.pdf. This guide is designed to help with the basic fundamentals of trade finance and to provide general information about common techniques of export financing.**

- When an organization does not engage in competition and instead uses a "shopping" process (perhaps comparing prices from catalogs or other freely disseminated information), the seller dictates payment terms and the methods of funds remittance it deems acceptable.

Payment terms can strongly influence the price of goods available to reproductive health (RH) purchasers in two ways:

- If terms put forward by the buyer under an international competitive bidding procedure seem unfavorable to potential suppliers, they will be unlikely to bid, competition will be limited, and prices may be higher as a result of the limited competition.
- International suppliers often charge higher prices to offset perceived risks, including those associated with the commercial, economic, and political situations evident in developing and transitional countries. Attractive, secure payment terms can lower or eliminate these perceived risks, benefiting the buyer with lower pricing.

1. Payment Terms

There are basically four payment terms used in international commerce, and they may be combined:

a. Cash in Advance (high risk to buyer; low risk to seller)

The buyer, after purchasing the commodity under the original contract, sends the seller "cash" prepayment for the entire shipment. (Methods of funds remittance are discussed in Section 2 below.) The seller, upon receipt of the cash advance, makes shipment to the buyer and provides all the necessary shipping documents.

This method of payment involves direct buyer/seller contact without commercial bank involvement and is therefore inexpensive. However, the buyer faces a very high degree of payment risk while retaining little recourse against the seller for poor-quality goods or incorrect or incomplete documentation, and there is a possibility that an unscrupulous seller may never deliver the goods even though the buyer has made full prepayment.

Full prepayment is appropriate for RH purchasers under special circumstances: United Nations agencies (such as the United Nations Population Fund and the United Nations Children's Fund) and a few other reputable public-health nonprofit organizations offer low-cost, good-quality health-sector goods, such as contraceptives, vaccines, essential drugs, and related supplies, on a noncompetitive, full prepay basis.

b. Open Account or "On Account" (low risk to buyer; high risk to seller)

This payment method is virtually the opposite of cash in advance. In this option, the seller essentially extends credit to the buyer. Upon shipment, the seller arranges for the preparation of the normal documents (such as bills of lading and original invoices) and presents these to the buyer directly, without the involvement of a commercial bank. The buyer then pays the seller directly upon receipt of the documents. When the buyer and the seller are in different countries, this payment may involve a wire transfer—thus, the engagement of a commercial bank and payment of fees is necessary.

Under an open account payment method, title to the goods passes from the seller to the buyer prior to payment; this subjects the seller to risk of default by the buyer. Furthermore, there may be a time delay in payment, depending on how quickly documents are exchanged between seller and buyer. While this payment term involves the fewest restrictions and low cost for the buyer, it also presents the seller with the highest degree of payment risk.

Open accounts can be appropriate when the buyer and the seller have a long-term relationship involving a level of mutual trust.

c. Documentary Collection (low risk to buyer; moderate to high risk to seller)

This method of payment is primarily used for ocean shipment. It is generally inapplicable for goods shipped by air since they would arrive well before the documents.

Under a documentary collection, the seller makes shipment and then sends the shipping documents to its bank for collection. The seller's bank forwards these shipping documents along with a collection letter to the buyer's bank, which, in turn, sends a collection notice to the buyer. The buyer either makes payment upon receiving the notice and prior to possessing the shipping documents, or, by prearrangement, the seller accepts a time draft obligating the buyer to pay at a future date. Only after payment or acceptance does the buyer receive the original shipping documents, which confer title to the goods.

The banks involved in transferring documents and payments do not guarantee payment or absorb any other form of risk in this type of transaction. This is reflected in costs to the customer. Fees for services rendered by the bank might include:

- Transmitting funds.
- Issuing banker's drafts.
- Receipt of transfers.
- Clearing foreign checks.

The major advantage of the cash against documents payment method for the buyer is the low cost versus opening a letter of credit (L/C). The advantage for the seller is that it can receive full payment prior to releasing control of the documents, although this is offset by the risk that the buyer will, for some reason, reject the documents (or that they will not be in order). Since the cargo would already be loaded (to generate the documents), the seller has little recourse against the buyer in cases of nonpayment.

This method may be appropriate when transaction values are less than US$10,000 or when the transaction is between parties that have begun to develop a relationship of trust.

d. Letter of Credit (low risk to seller; low risk to buyer)

L/Cs are discussed in detail in Section C: Letters of Credit. The following paragraphs briefly describe how an L/C works.

The buyer, after concluding a contract with a seller, applies to a commercial bank for an L/C in favor of the seller, which is called the beneficiary. The buyer, which is called the applicant, normally deposits funds in the opening bank to cover the amount of the credit, or instructs the bank to set aside funds that are already on deposit. The bank, through its issuance of the L/C, promises to pay the named party beneficiary when that party proves it has met the terms and conditions mentioned in the L/C as verified by presentation of conforming documents. Essentially, the bank enters into a contract with the seller in which it takes the place of the buyer and becomes responsible for the payment.

The main advantage of an L/C for the seller is that it is guaranteed payment upon performance. The seller also may be able to finance related materials and labor by assigning proceeds of the L/C. The main advantage for the buyer is that its money will be safe if the seller defaults. In addition, interest (or other consideration) will continue to accrue on deposited funds until the goods are shipped. An important advantage for RH purchasers is that the L/C can be written in a way that enforces quality assurance provisions in the

contract by linking proof of compliance to payment. On the downside, the existence of an L/C does not obligate the seller to ship the goods purchased by the buyer, and fees could reach 1 percent of the face amount of the L/C.

Depending on what has been negotiated, bank charges may be placed against (for the account of) a buyer or may be shared by the seller. Rarely will all charges be for the account of a seller. If the charges are to be shared, the customary procedure is that each party will pay the applicable fees for its respective country and/or bank. Potential fees are listed in Letters of Credit, Section C.5.d.

e. Combination of Payment Terms

Many contracts use a combination of the payment terms mentioned above. For example, a combination may consist of a down payment (partial cash in advance) covering 10 percent of the full price, an L/C covering most of the balance (perhaps 80 percent), and a retention payment covering the rest of the full price (perhaps 10 percent).

- **Down payment:** A down payment induces the seller to begin performance without the buyer paying the entire agreed price in advance. The disadvantage is the possibility that the seller may never deliver the goods even though it has the buyer's down payment. This option is combined with one of the other options to cover the full cost of goods.
- **L/C for a percentage of the cost of goods:** The L/C provides a guarantee to the seller that it will get paid upon performance, but allows the buyer to keep control of the funds until the goods are shipped.
- **Retention funds:** When agreed in a contract, the buyer withholds a percentage of the agreed price until it has received the goods and determined that they are as ordered and in acceptable condition. This is advantageous for the buyer as a tool for enforcing quality requirements. The disadvantage for the seller is the risk that it will not get paid the final amount even if the goods shipped are in good order. Retention is most appropriate for domestic procurement contracts when a risk of poor-quality goods is involved. RH programs purchasing in the international marketplace should be aware that this tactic may limit competition because of the perceived risk it poses to potential sellers.

2. Methods of Funds Remittance

Contracts always stipulate payment terms (e.g., L/C or cash against documents), but the actual process by which money will transfer from one party to another needs to be

considered as well. The following discussion about funds remittance methods recognizes two essential parts: type of payment and form of payment.

a. Types of Payment

Under the general heading of funds remittance, there are three types of payment:

At sight

At sight means payment will be made immediately after:

- Presentation of a sight draft (bill of exchange).
- Presentation of conforming documents.
- The stipulated bank has had reasonable time to examine documents.
- The documents are found to be in order.

Deferred payment

Deferred payment means payment will be made at a specified or determinable future date stipulated in an L/C or documentary collection, provided that the documents are found to be in order. An example might be a payment made 60 days after the date of transport documents or invoice date. No draft is necessary under this type of payment.

Acceptance

Acceptance is similar to deferred payment, but a "term draft" (also called a "usance draft")[§§§] is presented to a stipulated bank along with the other required documents. Once the documents and draft are accepted, then the draft will be drawn on and payable at a future date as stipulated in the L/C or another payment vehicle. For example, 30 days' sight would mean that payment would be made to the seller 30 days after the remitting bank has looked at, reviewed, and accepted the documents.

b. Forms of Payment

Checks

A check is a negotiable instrument issued against deposited funds to pay a specified amount of money to a specific person or company on demand. Checks can be drawn on banks located in any country depending on where a buyer holds accounts. A check drawn on a bank in a seller's country is less risky since the seller can verify availability of funds. The most risk is found with a company check drawn on a bank outside the seller's country.

[§§§] **Demand for payment at a stated future date.**

In order for the seller to receive funds, a check must be deposited or cashed. If the check is deposited in a seller's account and the check is drawn on an overseas bank, the funds will not be available to the seller until the check is sent overseas for clearance and the funds are transferred to the seller's bank. The relationship between the banks involved, the countries involved, and the currency of the check will determine how long it will take and the fees that will be charged.

Banker's drafts

Banker's drafts are similar to checks. However, they are time drafts drawn on a bank by another bank and once accepted, they become unconditional obligations of the bank to honor at maturity. (A time draft is an instrument requesting payment at a future time to a third party.)

Electronic funds transfers

Electronic funds transfers are also commonly known as wire transfers. They are a quick, effective method of transferring money between buyers and sellers, particularly when the buyer and the seller are located in different countries. Bank fees for this service vary; they may be a percentage of the transaction (possibly 1 to 3 percent) or a flat fee agreed upon with the customer.

The process works as described below.

1. A buyer contacts its bank (the remitting bank) and arranges for the funds transfer to the seller's bank, giving:
   - The seller's full name and address.
   - The seller's bank name, location, American Bankers Association identification number, and routing number.
   - The seller's account number.
   - The exact name in which the account is maintained.
   - The amount to be wired.
   - The currency of the funds to be wired.
2. The remitting bank responds to the instructions of the buyer by issuing a payment order to the receiving bank requesting the payment to be credited to the third-party beneficiary (seller). Payment orders are sent by telex or an interbank

telecommunication system known as SWIFT.[****] The authenticity of these messages is ensured by sophisticated data encryption. However, the receiving bank must be a correspondent of the remitting bank at least to the extent that the receiving bank can verify the authenticity of the instructions.

Other methods of funds transfer

Several other methods of funds remittance exist, but they are generally not used for large international transactions for the following reasons:

- Cash or bank notes: due to the risk of loss or forgery payment types.
- Credit cards: due to credit limits and high fees.
- Money orders: due to limits on amounts and currencies.

[****] SWIFT stands for Society for Worldwide Interbrain Financial Telecommunication. It is a computer-based, standardized message-writing system that connects worldwide participating banks, primarily for the purpose of communicating payment information. It is used extensively in L/C operations.

E. Prequalification

As described in Module 6: Developing Bidding Documents and Inviting Offers, prequalification focuses on two separate aspects of the selection process:

- Quality, safety, and efficacy of the product.
- Reliability of the supplier.

Prequalification may be conducted by the purchaser, purchasing agencies, and the World Health Organization (WHO). Prequalification includes gathering information on product quality and supplier reliability; inspecting sites, products, and samples; and conducting laboratory testing of products with high potential for problems. Prequalification may be used to develop lists of preapproved suppliers for a bid, either annually or once every several years. It is particularly useful in the case of international competitive bidding, when there is concern that advertised bid notices will elicit a large number of unsuitable offers and the procuring entity has only limited resources with which to perform detailed evaluations.

Typically, prequalification status must be reviewed on a routine basis (normally every 1 to 3 years but at least once every 5 years). Suppliers of a product remain prequalified unless there are recalls or noncompliance problems. Previously nonqualified suppliers should be allowed to apply for prequalification again if they wish.

1. World Health Organization Prequalification

WHO has prequalification programs for vaccines, diagnostics, medical devices, and medicines. Reproductive health products are included in the medicines program. The WHO Prequalification of Medicines Programme results in a list of prequalified products and manufacturers that comply with unified international standards. The guiding principles of the prequalification process require that it be:

- **Voluntary:** Manufacturers can freely choose to participate or not to participate; however, countries will be increasingly required to use the WHO prequalification process for procurement of donor-funded products, as it is becoming widely required by donors such as the Global Fund to Fight AIDS, Tuberculosis and

Malaria (Global Fund) and other agencies within the Reproductive Health Supplies Coalition.[††††]

- **Legitimate:** The general procedures and standards for prequalification are reviewed and approved by the WHO Expert Committee system, which includes all WHO member states and governing bodies.
- **Endorsement:** The prequalification system was presented to and supported by the 10th and 11th International Conference of Drug Regulatory Authorities (ICDRA) meetings in 2002 and 2004. ICDRA is a forum for drug regulatory authorities of WHO member states that strengthens collaboration and identifies priorities for the regulation of medicines.
- **Transparent:** All information from the prequalification process is available on the WHO prequalification website. The prequalification process for medicines and devices is open to both innovator (patented) products and generic products. For prequalification to work, there must be multiple manufacturers participating. The WHO Prequalification Programme is efficient in recognizing that some medicines have been through rigorous regulatory testing by credible agencies.
- **Capacity-strengthening:** The prequalification process helps manufacturers strengthen capacity. If a manufacturer does not initially meet standards, it receives a specific report of findings and recommendations for improvements. Prequalification is not a strict pass/fail process. Manufacturers can make improvements and correct deficiencies and then resubmit and continue to pursue prequalification.

Roles and responsibilities in the WHO prequalification process are divided as follows:

- WHO provides technical support, scientific support, and a guarantee that international norms and standards are incorporated and adhered to throughout the entire prequalification process (including assessment, inspection, and quality control).
- For medicines, the assessment of dossiers and inspection of manufacturing sites are primarily done by qualified personnel appointed by WHO from the national regulatory authorities of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S, http://www.picscheme.org) and the International Conference on Harmonisation of Technical Requirements for

[††††] The Reproductive Health Supplies Coalition is a global partnership of public, private, and nongovernmental organizations dedicated to ensuring that all people in low- and middle-income countries can access and use affordable, high-quality supplies to ensure their better reproductive health. For more information, see http://www.rhsupplies.org/.

Registration of Pharmaceuticals for Human Use (ICH, http://www.ich.org) member countries. (See Section I: Product Inspection and Testing and Section K: Regulatory Authorities for more information on the PIC/S and ICH.) WHO also arranges for site inspection of manufacturers to assess compliance with current good manufacturing practices (cGMPs). A representative of the national regulatory authority traditionally accompanies the inspection team for the site inspection.

- Condom and intrauterine device prequalification is overseen and implemented by the United Nations Population Fund on behalf of WHO and is supported by independent technical experts with in-depth knowledge and expertise in the manufacturing and quality assurance (QA) issues related to these products.

WHO prequalification systems cover these QA activities:

- Development, establishment, and promotion of norms and international standards to ensure safety and QA for products.
- Assistance to countries in building national regulatory capacity through networking, training, and information-sharing.
- Provision of expertise and technical assistance through various activities in the areas of QA, regulation and legislation, safety, and efficacy.
- Provision of guidance in regulation, safety, and QA.
- Assessment of data from manufacturers regarding the quality, safety, and efficacy of their products, including details about the purity of all ingredients used in manufacturing, data about finished products (such as information about stability), and the results of *in vivo* bioequivalence tests (clinical trials conducted in healthy volunteers).
- Performance of inspections at the manufacturing sites and assessment of working procedures for compliance with WHO cGMPs.
- Shipment of products to professional control testing laboratories for analytical verification of quality.
- Requalification of all medicines after 1 to 3 years and at a minimum every 5 years.
- Performance of random quality control testing of prequalified medicines that have been supplied to countries.
- Investigation and resolution of complaints.

- Monitoring of supplier quality and taking corrective action if standards are not maintained.

The international donors and programs described below endorse the WHO Prequalification Programme.

2. Global Fund to Fight AIDS, Tuberculosis and Malaria

The Global Fund was created to dramatically increase resources to fight three of the world's most devastating diseases—HIV/AIDS, tuberculosis (TB), and malaria—and to direct those resources to areas of greatest need. The Global Fund is a partnership between governments, civil society, the private sector, and affected communities.

The Global Fund's procurement policy allows for three options in procuring single- or limited-source pharmaceutical products (products for which there are no public monographs for finished dosage form in the International, British, or United States Pharmacopoeia). These options include:

1. Products prequalified by the WHO Prequalification Programme.
2. Products authorized by a stringent regulatory authority (SRA). An SRA is defined as a national regulatory authority participating in ICH and its affiliates as defined by the Global Fund or those countries participating in the PIC/S.
3. If there is only one or no equivalent pharmaceutical product that meets the standards of either (1) or (2), then grant funds may be used to procure another equivalent finished pharmaceutical product, provided that such a product is selected in accordance with the following and recommended for use by a Global Fund expert review panel:

    a. The manufacturer of the finished pharmaceutical product has submitted an application for prequalification of the product by the WHO Prequalification Programme and it has been accepted by WHO for review.

    OR

    b. The manufacturer of the finished pharmaceutical product has submitted an application for marketing authorization to an SRA and it has been accepted for review by the SRA.

    AND

c. The finished pharmaceutical product is manufactured at a site that is compliant with cGMP standards that apply for the relevant product formulation, as verified after inspection by:
   - the WHO Prequalification Programme, OR
   - an SRA, OR
   - a regulatory authority participating in the PIC/S.

See the *Guide to the Global Fund's Policies on Procurement and Supply Management* (2006) at http://www.theglobalfund.org/documents/psm/pp_guidelines_procurement_supplymanagement_en.pdf for more information about Global Fund procurement policies regarding QA.

3. Roll Back Malaria Partnership

The Roll Back Malaria (RBM) Partnership was established in 1998 by WHO, the United Nations Children's Fund (UNICEF), the United Nations Development Program, and the World Bank to provide a coordinated global approach to fight malaria. Since then, the RBM Partnership has expanded to include a wider range of partners—including malaria-endemic countries, bilateral and multilateral development partners, the private sector, nongovernmental and community-based organizations, foundations, and research and academic institutions.

Partners are working together to scale up malaria control efforts at the country level, to coordinate their activities in avoidance of duplication and fragmentation, and to ensure optimal use of resources.

A key role of the RBM Partnership is to lead continuing advocacy campaigns to raise awareness of malaria at the global, regional, national, and community levels.

The RBM Partnership does not procure malaria commodities. UNICEF provides procurement services in support of RBM and is the world's largest buyer of insecticide-treated bed nets. All mosquito nets procured by UNICEF must comply with the WHO pesticide evaluation scheme, and all anti-malarial medicines must be WHO prequalified.

4. Stop TB Partnership

The Stop TB Partnership was established in 2000 to realize the goal of eliminating TB as a public health problem. It comprises a network of more than 500 international organizations, countries, public- and private-sector donors, and governmental and nongovernmental

organizations that have expressed an interest in working together to achieve this goal. WHO is a partner in the Stop TB Partnership, as is the Global Drug Facility (GDF).

The GDF is a mechanism to expand access to and availability of high-quality anti-TB medicines and diagnostics to support the Stop TB strategy. The GDF both supplies donated medicines and procures medicines to support national TB programs. The GDF offers a standardized WHO-approved catalog of anti-TB medicines and formulations designed to promote the products prioritized by the Stop TB Partnership.

All medicines supplied by the GDF must be WHO prequalified or reviewed and approved by a committee of independent experts pending WHO prequalification.

5. Clinton Foundation

The mission of the Clinton Foundation is to strengthen the capacity of people throughout the world to meet the challenges of global interdependence. To advance this mission, the Clinton Foundation has developed programs and partnerships in the areas of health security; economic empowerment; leadership development and citizen service; and racial, ethnic, and religious reconciliation.

The Clinton Foundation's quality standards mirror the Global Fund requirements. The Foundation "is committed to the sustainable supply of high-quality ARVs [antiretrovirals], consistent with the specifications of dossiers approved by the World Health Organization or a stringent regulatory authority such as the USFDA [United States Food and Drug Administration]."

6. World Bank

While the World Bank does not limit its funded projects to procuring only WHO-prequalified products, it strongly supports the WHO Prequalification Programme, as is evidenced by statements and requirements in its published documents.

The World Bank recognizes that not all countries have the capacity to conduct a valid product prequalification process. In its publication *Battling HIV/AIDS: A Decision Maker's Guide to the Procurement of Medicines and Related Supplies* (2004), the World Bank strongly recommends that in those circumstances, WHO-prequalified HIV/AIDS medicines should be procured.

In the World Bank's recent announcement of its partnership with the Global Fund, the Clinton Foundation, and UNICEF, the Bank announced that its quality standards for

antiretrovirals purchased under this partnership would be the same as those of the Clinton Foundation (i.e., prequalified by WHO or an SRA).

The World Bank also depends on WHO standards for malaria diagnostic test kits and insecticide-treated bed nets approved by the WHO pesticide evaluation scheme.

Resources

Clinton Foundation Information Center Resources

The Clinton Foundation website has an HIV/AIDS initiative information center that details antiretroviral pricing, supplier requirements, and current proposal opportunities.

http://www.clintonfoundation.org/what-we-do/clinton-hiv-aids-initiative/information-center-resources

Global Fund Website

This website is the central resource center for all Global Fund activities, resources, policies, and reports.

http://www.theglobalfund.org/en/

Global Fund Quality Assurance Information

This website details the new QA policy for procurement of commodities under Global Fund grants.

http://www.theglobalfund.org/documents/psm/Annex1-%20FullTextRevisedQualityAssurancePolicy_en.pdf

Roll Back Malaria Partnership Website

The RBM Partnership is the global framework to implement coordinated action against malaria. It mobilizes for action and resources and forges consensus among partners. The Partnership is comprised of more than 500 partners.

http://www.rollbackmalaria.org

Stop TB Partnership Website

The Stop TB Partnership, called the Stop TB Initiative at the time of its inception, was established in 1998. Its aim is to realize the goal of eliminating TB as a public health problem and, ultimately, to obtain a world free of TB. It comprises a network of international organizations, countries, donors from the public and private sectors, and governmental and

nongovernmental organizations and individuals that have expressed an interest in working together to achieve this goal.

http://www.stoptb.org

***Battling HIV/AIDS: A Decision Maker's Guide to the Procurement of Medicines and Related Supplies* (International Bank for Reconstruction and Development/ World Bank, 2004)**

This guide sets out principles and advice for the procurement of HIV/AIDS medicines and related supplies for programs scaling up antiretroviral therapy and associated health services, such as basic and palliative care, disease prevention, treatment of opportunistic infections, and laboratory tests.

http://siteresources.worldbank.org/INTPROCUREMENT/Resources/Technical-Guide-Procure-HIV-AIDS-Meds.pdf

WHO Prequalification Programme

This website details all major topic areas for the WHO Prequalification of Medicines Programme, including current Expressions of Interest, prequalification lists, and details about the process. In close cooperation with national regulatory agencies and partner organizations, the Prequalification Programme aims to make high-quality priority medicines available for the benefit of those in need. This is achieved through its evaluation and inspection activities, and by building national capacity for sustainable manufacturing and monitoring of medicines.

http://www.who.int/prequal/

World Bank *Standard Prequalification Document: Procurement of Health Sector Goods* (Trial Edition, 2002)

The standard prequalification document is used following the advertisement of a general procurement notice. The template outlines an invitation for prequalification for a specific procurement notice. It is intended primarily for use in prequalifying applicants that express an interest in bidding on the supply of health-sector goods.

http://web.worldbank.org/WBSITE/EXTERNAL/PROJECTS/PROCUREMENT/0,,contentMDK:21890171~menuPK:84284~pagePK:84269~piPK:60001558~theSitePK:84266~isCURL:Y,00.html

World Bank *Technical Note*

This technical note, which accompanies the *Standard Bidding Document: Procurement of Health Sector Goods*, includes a helpful annex discussing the pros and cons of prequalification.

http://siteresources.worldbank.org/PROCUREMENT/Resources/health-tn-ev2.doc

F. Procurement Agents

There are various scenarios when purchasers have the option of hiring a third party to represent them. Third-party procurement agents buy products on behalf of purchasers and charge a fee for their services, but the purchasers retain control over all transactions and decisions.[1] The actual work conducted by procurement agents varies, but it revolves around two core activities: assuring product quality and negotiating competitive prices and purchasing terms.[2] Agents may take on the responsibility for developing specifications, prequalifying suppliers, soliciting quotations, selecting a supplier, awarding contracts, and arranging for product testing and shipping.[3]

Success depends on selecting a competent agent. When choosing an agent, procurement officials should check the training and experience of agency personnel, the agent's contract and performance history, licensing and registration, and references.[4] In order to get the best possible arrangements, procurement units should ask candidate agencies to compete for contracts and should include performance criteria in the contracts to ensure responsiveness and professionalism.[2,5]

Ideally, an agent hired to procure reproductive health commodities should have regular dealings with such manufacturers, considerable experience with prequalification and other procurement tasks, and a track record of procuring good-quality products at competitive prices. For example, the United Nations Population Fund (UNFPA) is more experienced in family planning, and in procuring contraceptives at highly competitive prices, as compared with other United Nations agencies, such as the United Nations Development Programme (UNDP) and the United Nations Children's Fund (UNICEF). However, governments' decision-making around procurement agents may be influenced by donor requirements. For instance, the government of Honduras relied on UNDP for contraceptive procurement because it was easier to incorporate contraceptives into its health loan package from the World Bank.[5]

Procurement officials should avoid local middlemen who call themselves procurement agents but are actually distributors who sell products from prearranged sources. They do not conduct true competitive procurements on behalf of purchasers.[1]

While international nongovernmental organizations (NGOs), such as Missionpharma and the IDA Foundation, and United Nations agencies such as UNFPA are often called procurement agents, it should be noted that they sometimes function like traditional distributors or

wholesalers.[2,4] For example, many countries essentially engage UNFPA as a sole-source supplier for contraceptives. They request a price quotation for the supplies they want and place an order, on the assumption that UNFPA has access to competitive international prices.

1. Management Burden

The single most compelling reason to hire a procurement agent is that local officials may lack the resources, internal capabilities, and experience to procure products directly from suppliers.[1,3] Hiring an agent can give a program access to complex procurement mechanisms, such as international competitive bidding, that are beyond its own capacity.[4]

While hiring a procurement agent reduces the management burden considerably, it does not eliminate it. In addition to forecasting, procurement officials need to know how to do consultant contract management, the most important element of which is closely monitoring and managing the agent's performance.[6,7] Procurement officials should make sure that the agent is getting competitive prices, that the products are of high quality and are being delivered on time, and that the agent continues to represent the best procurement option given local circumstances.[5]

2. Impact on Costs

Because of their experience with competitive bidding and price negotiations, commercial (private for-profit) procurement agents may be able to arrange better unit prices than national procurement officials could get on their own. Even when procurement agents do not conduct competitive bidding, they can use their knowledge of international reference prices and the prices paid by other countries to strengthen their negotiating position.[5]

International NGOs and United Nations agencies that act as procurement agents can offer customers economies of scale; because they purchase large volumes of products for many countries, they can access competitive international prices.[8] For example, because International CONtraceptive & SRH Marketing Ltd (ICON) conducts regular procurements to supply its International Planned Parenthood Federation member associations worldwide, it can take advantage of bulk purchasing to lower contraceptive costs.[9] From the perspective of the purchaser, ICON and UNFPA essentially function as a pooled procurement mechanism on a global scale. In a similar fashion, the Stop TB Partnership's Global Drug Facility uses a procurement agent—UNDP's Inter-Agency Procurement Services Office (IAPSO)—to purchase tuberculosis drugs for countries around the world from prequalified suppliers via limited international competitive bidding, with the products shipped directly to

the recipient countries. Global Drug Facility prices are, on average, one-third less than previous international bids because its bulk purchases and pooled procurement enabled IAPSO to negotiate prices with manufacturers.[10]

Many countries in Latin America (including the Dominican Republic, El Salvador, Honduras, and Peru) have signed agreements with UNFPA that established the agency as a procurement agent in order to gain access to international prices. All of these countries have legal restrictions on international bidding in order to promote domestic industry. Purchasing from UNFPA allows them to procure contraceptives at competitive prices in international markets without having to directly issue an international bid or contract with an international manufacturer. Their agreements with UNFPA have led to large cost savings. For example, in 2005, UNFPA was able to supply contraceptives (including oral contraceptives, condoms, intrauterine devices, and injectable contraceptives) to the Dominican Republic at prices that were one-sixteenth of those offered by local suppliers. El Salvador's savings were estimated at close to US$3 million per year in 2004 and 2005.[5]

United Nations agencies may also gain price advantages from special arrangements that excuse their procurements from some taxes and tariffs. In El Salvador, for example, contraceptives purchased through UNFPA with public-sector funds are exempt from import taxes if they are introduced into the country using a presidential decree, although value added tax still applies. In Peru, the original terms of the agreement signed by the Ministry of Health exempted contraceptives procured by UNFPA from taxation, but that changed in 2005, effectively raising contraceptive costs.[5]

One cannot assume that a United Nations agency, private procurement agent, or an international NGO will always offer the lowest prices. In El Salvador, for example, local suppliers charge far less than UNFPA for condoms, so the government has left the decentralized local purchase of condoms in place, even as it has shifted the remainder of its contraceptive procurement to UNFPA. Likewise, a market study in Peru found that UNFPA's prices were lower than local suppliers for intrauterine devices, similar for injectable contraceptives, and 25 percent higher for oral contraceptives.[5]

Procurement agents of all kinds typically charge a percentage fee based on the value of the purchase to cover handling and administrative costs. Procurement fees typically range from 5 to 10 percent, in addition to product and shipping costs.[9] UNICEF also charges a refundable 10 percent buffer to cover market and foreign exchange fluctuations. Because fees are calculated on a percentage basis, fees—and agents' profits—increase with the size of the order even though it may not involve any more work.[2]

There is a real possibility that agents' fees may offset any price advantage they offer.[4] Some price analyses have found that UNFPA's contraceptive prices are often lower than other prices available, even with the addition of a 5 percent administrative fee.[5] Other analyses have found that administrative fees charged by UNICEF and the Pan American Health Organization, for example, have raised the total cost of vaccines, for instance, up to or beyond the lowest vaccine prices offered directly to public-sector markets.[6]

3. Impact on Quality

Procurement agents generally take on the responsibility of assuring the quality of the products they procure, which can be a great advantage for countries that lack the local capacity for quality control. For example, UNFPA, the United States Agency for International Development through John Snow, Inc., Population Services International, and ICON purchase condoms using model specifications and undertake both the prequalification of manufacturers and lot-by-lot compliance testing.[3]

As organizations like UNFPA and KfW[‡‡‡‡] have expanded their sourcing from United States- or Europe-based research and development pharmaceutical companies to developing-country manufacturers of generic formulations, they have necessarily devoted more time to assessing products and facilities. Many generic manufacturers in developing countries cannot obtain United States Food and Drug Administration or European Medicines Agency approval, so UNFPA and KfW are increasingly conducting their own quality and safety assessments, including site visits to assess facility conditions, compliance with ISO 9000[§§§§] standards, and current good manufacturing practices. Commercial agents also conduct inspections of factories and sample products onsite.[11] For more information, see Section H: Product Quality Assurance.

4. Impact on Reliability of Supplies

Some international NGOs and United Nations affiliates, such as ICON and UNFPA, have lists of prequalified suppliers, procurement framework contracts in place, or existing supply

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‡‡‡‡ KfW Bankengruppe of Germany gives impetus to economic, social, and ecological development worldwide. It offers support to encourage sustainable improvement in economic, social, ecological living, and business conditions, among others, in the areas of small and medium-sized enterprise, entrepreneurialship, environmental protection, housing, infrastructure, education finance, project and export finance, and development cooperation.

§§§§ Maintained by the International Organization for Standardization, ISO 9000 is a family of standards for quality management systems that is administered by accreditation and certification bodies. It includes a set of procedures that cover all key processes in the business, including monitoring processes to ensure they are effective; keeping adequate records; checking output for defects, with appropriate and corrective action where necessary; regularly reviewing individual processes and the quality system itself for effectiveness; and facilitating continual improvement.

contracts with manufacturers, all of which can decrease lead times. They may even maintain stocks of products for immediate distribution.[3,9] For example, UNFPA's Global Contraceptive Commodity Programme keeps buffer stocks of essential contraceptives and reproductive health kits at suppliers' premises so that UNFPA can respond immediately to emergency requests from developing countries.[12]

Most procurement agents, including UNFPA, deliver only to a country's port of entry.[2] This leaves national procurement units with the responsibility for arranging and paying for all customs requirements, product registration, and other bureaucratic procedures; transport and insurance; and the receipt, inspection, unloading, storage, and distribution of the goods. This, along with the long distances the products may be traveling, can create delays in product delivery.[5] It is possible, however, to contract with a procurement agent to take full responsibility for transportation and delivery.

5. Vulnerability to Corruption and Political Interference

Hiring a respected procurement agent with good references can help reduce the risk of corruption because it removes purchasing decisions from local officials. The clear procurement procedures followed by most international NGOs and United Nations affiliates also improve the transparency of the procurement process.

However, vigilance is still required, especially when unfamiliar procurement agents come forward in response to a bid.[4]

6. Policy and Legal Environment

National product registration and procurement laws still apply when procurement agents are using public-sector funds to purchase products. However, United Nations agencies acting as procurement agents may receive special treatment. In Paraguay and Peru, for example, agreements between the Ministries of Health and UNFPA exempt public-sector contraceptive purchases from legal requirements for public bids.[5] The same exceptions cannot be applied to international NGOs or commercial companies that act as procurement agents.

7. Funding Issues

Procurement agents can be hired regardless of the funding source; the funds may be internally generated, come from donors or lenders, or consist of pooled donor funds

associated with a sector-wide approach.[*****5] In fact, some donors encourage the use of procurement agents and even make the arrangements themselves. In Cambodia, for example, all public-sector contraceptive supplies are funded and procured by the donor community, principally by KfW. Under an agreement with the government, external consultants based in Germany undertake procurement on the government's behalf in collaboration with relevant government departments.[8] Similarly, the United Kingdom Department for International Development often contracts directly with third-party procurement agents to purchase commodities on behalf of recipient countries, while other bilateral donors contact UNFPA to conduct procurements through direct funds transfers from donors.[9]

UNFPA, like other United Nations agencies, requires advance payment for all contraceptives being purchased before it will begin the procurement process. This can pose obstacles in some countries. First, some countries may lack the political will and/or fiscal ability to commit the necessary sums of money up front.[5] Second, government procurement rules may forbid this kind of advance payment.[6] In contrast, ICON gives its affiliates the option of receiving products in several scheduled shipments throughout the year, which spreads out payments and provides the ability to gather funds throughout the year.[5]

8. When is Hiring a Procurement Agent Appropriate?

Procurement agents can be a good resource for large orders of standard commodities, since they frequently have access to competitive international prices. However, they are also a good option for small orders that do not justify competitive bidding. Agents may be able to arrange a small purchase as part of a larger bulk order, thus reducing costs.[3] Alternatively, they may be able to use their knowledge of international reference prices to negotiate a competitive purchase price.[13]

United Nations affiliates and international NGOs may not make ideal procurement agents when a program wants to be in control of every detail of the products ordered, including packaging, labeling, and brand.[3,6] Their pooled procurement approach may preclude customization unless the order is large and the lead time is long. Another potential

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[*****] A sector-wide approach is an approach to international development that brings together governments, donors, and other stakeholders within any sector. It is characterized by a set of operating principles rather than a specific package of policies or activities. The approach involves movement over time under government leadership toward broadening policy dialogue, developing a single-sector policy (that addresses private- and public-sector issues) and a common realistic expenditure program, common monitoring arrangements, and more coordinated procedures for funding and procurement.

limitation is that procurement agents based in countries with strong patent protections for drugs may not be able to arrange for the quality testing and importation of generic drugs.[14]

Table 1. Impact of Different Procurement Mechanisms

Procurement Mechanism	Effect on Prices	Quality Safeguards	Lead Times	Management Capacity Required	Vulnerability to Corruption and Political Interference	Appropriate for?
United Nations or NGO procurement agent	Very positive, but fees may offset	Very strong	Varied	Low	Low	-Orders of all sizes -Standardized items
Private procurement agent	Positive, but fees may offset	Strong	Moderate	Moderate	Moderate	-Orders of all sizes

Table 2. Key Advantages and Disadvantages of Different Types of Procurement Agents

Procurement Model or Mechanism	Advantages	Disadvantages
United Nations or NGO procurement agent	- Low international prices - Strong quality assurance - May be able to make emergency deliveries from stock-on-hand - Minimizes demands on national procurement staff - Specialist knowledge of contraceptive procurement	- Relatively high fees - May require advance payment - Only delivers to port of entry, leaving customer responsible for clearing goods through customs
Private procurement agent	- Competitive prices - Strong quality assurance - Short lead times - Minimizes demands on national procurement staff	- Relatively high fees - May lack specialized product expertise

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G. Procurement Models: Centralized vs. Decentralized

Deciding whether to purchase centrally or to delegate the tasks of procurement to regional and local facilities is a system-wide financial control issue. Each alternative is examined below. There are good arguments for both alternatives, as well as weaknesses. Each is summarized in two tables at the end of this section.

1. Centralized Procurement at the National Level

a. Central Medical Stores

In most developing countries, the government owns, funds, and manages the supply chain for the public-sector health system.[1] Procurement has historically been the responsibility of the central medical stores (CMS), which typically is a unit of the Ministry of Health. Some countries separate procurement and distribution functions, such as Zambia, where the Ministry of Health manages a separate procurement unit and a CMS (Medical Stores Limited) for warehousing and distribution.

The CMS may:

- Directly manage the bidding process, using its own personnel.
- Hire a third-party procurement agent to act on its behalf.
- Retain responsibility for some functions while contracting out others, such as hiring private operators to provide transportation, or contracting with private laboratories to conduct quality testing.[3]

Historically, many CMS systems did not have good track records; they allowed the availability of drugs in the public sector to deteriorate in many developing countries. CMS units have had difficulty coping with the expanding number and types of commodities to be purchased, especially as financial resources have decreased. They have experienced problems with financial management, quantification of requirements, management of bids, warehouse management, transport, and physical security of products. Political influence and weak staff discipline have also contributed to their poor performance.[1]

b. Parastatals and Autonomous Supply Agencies

In recent years, many governments have tried to improve the performance of centralized procurement systems by shifting from a CMS or government procurement unit to either a

parastatal organization or autonomous supply agency (ASA).[1] A parastatal organization is owned or controlled wholly or partly by the government, but has been granted the autonomy to promulgate its own financial and procurement regulations. In contrast, an ASA is managed by an independent agency that reports to the government or by a private firm under government contract.[2] Both parastatals and ASAs are overseen by a board of directors that includes representatives from outside government and that has the freedom to appoint qualified managers without political pressure.[1] For example, in 2000, Kenya transferred its central and regional medical supply stores to a parastatal organization, the Kenya Medical Supplies Agency (KEMSA). KEMSA's board of directors includes representatives from the Kenya Medical Association.[2]

Replacing a CMS with a parastatal or ASA model reduces direct government management of procurement and theoretically can achieve the efficiency and flexibility associated with private-sector management and employment. For example, in 1970, Chile implemented a national ASA model described in the case study below. However, sufficient public-sector supervision still remains to ensure public health objectives, such as focusing on the provision of essential drugs rather than more profitable products.[3] While parastatals and ASAs may or may not operate on a nonprofit basis, ideally they can achieve greater value for the money and improved drug availability than a CMS through more efficient management.[1] For example, in 1997, Tanzania created an ASA, the Medical Stores Department, to strengthen procurement management and increase cost effectiveness and efficiency. The Medical Stores Department uses international competitive bidding to achieve competitive prices and also has the ability to contract with outside procurement agencies.[2]

Case Study: Reforming Procurement in Chile

The Chilean national procurement agency for the National Health Service (CENABAST, *Central de Abastecimiento*) was founded in 1970 as a parastatal organization. A combination of weak management, limited staff skills, and inadequate monitoring led to poor results, including chronic stock-outs, overstocks, wastage, and corruption. To increase efficiency and reduce corruption, Chile:

1. Increased CENABAST's autonomy, transforming it into a semiautonomous agency.
2. Shifted many of its responsibilities, including prequalification of bidders, storage, and transport, to other health agencies and the private sector.

3. Created electronic systems to disseminate information and receive bids over the Internet.
4. Instituted new incentive structures that foster ethical behavior.

In Chile's decentralized health system, district health offices and hospitals can purchase from whatever source offers the best service or price. The CENABAST model is merely one of many alternatives. However, most choose to order from CENABAST because of the low prices and good quality that its centralized pooled procurement services offer.

After receiving consolidated information on contraceptive requirements for the public health system, CENABAST calls for bids. While these may be open to foreign firms, most are directed only to local suppliers that are preapproved and registered by the Public Health Institute to help assure product quality. Suppliers submit offers on specific products and quantities via computer and can reduce their offers after viewing information on low bids. This system, along with Chile's open economy and large market, helps CENABAST obtain competitive prices. CENABAST's autonomy and external auditing procedures help ensure transparency.

Sources: *Using Technology to Fight Corruption in Pharmaceutical Purchasing: Lessons Learned from the Chilean Experience* (Cohen and Montoya, 2001)[4]; *Options for Contraceptive Procurement: Lessons Learned from Latin America and the Caribbean* (Sarley et al., 2006).[5]

c. Impact on Costs

One of the greatest advantages of a centralized procurement system is its ability to achieve economies of scale. The central procurement unit—whether it is the Ministry of Health procurement unit, CMS, parastatal, or ASA—orders sufficient quantities to supply all of the facilities in the nation. These large orders can command lower prices from suppliers. At the same time, centralizing procurement reduces administrative costs.[1] However, these central units generally hold a monopoly on procurement. Lack of competition or other incentives means that staff members may feel little pressure to improve the quality of the services they offer or to seek the lowest possible prices.[1]

In Colombia, the nongovernmental organization Profamilia relies on a centralized procurement system to supply its 34 clinics, which together disburse the majority of the nation's contraceptive supplies.[5] A central office procures contraceptives from both local and international suppliers, depending on cost and availability. For instance, Profamilia imports injectable contraceptives, intrauterine devices, condoms, and emergency contraceptive pills, but purchases oral contraceptives locally. All supplies pass through a

central warehouse. Centralized procurement achieves lower prices because of bulk purchases made on behalf of all member clinics. By consolidating most administrative functions, Profamilia also has reduced the administrative costs of procurement while promoting the standardized implementation of institutional policies and quality control systems.

ASAs in Chile and Tamil Nadu, India, have also achieved significant cost savings. Hospitals in Chile saved an estimated US$4 million on drugs and medical supplies in 1997, in part because CENABAST reduced its margins (from 14 percent to 5 to 10 percent) and in part because competitive bidding processes lowered prices by 5 to 7 percent.[4] The Tamil Nadu Medical Services Corporation credits competitive procurement systems, prompt payment, and administrative efficiencies for considerable reductions in drug costs and shortages, even though it charges a 5 percent fee to cover its costs.[1]

d. Impact on Quality Assurance

Quality assurance (QA)—including the prequalification of suppliers and laboratory testing of contraceptive samples—makes heavy demands on a procurement unit's management and technical capacity.[2] However, it may be difficult for centralized procurement systems to hire the skilled and experienced personnel and build the laboratory infrastructure required. Low pay, limited promotions, and political interference in hiring and firing can make it even more difficult for a CMS to hire and retain skilled people than a parastatal or ASA.[2,6]

Therefore, centralized procurement units frequently choose to contract out some or all of the basic quality control functions. For example, CENABAST, in Chile, hires an international firm to accredit and prequalify local suppliers from which they solicit bids.[5] Hiring an independent outside laboratory to conduct product testing is also common.

e. Impact on the Reliability of Supplies

The CMS model has a poor track record for making timely deliveries and maintaining adequate inventories of drugs and contraceptives. Frequent stock-outs are one of the factors that have undermined support for the CMS in many countries. Two weaknesses contribute to this problem: poor communication with health facilities about the number and types of products they need, and inefficient distribution systems.[7]

f. Management Burden

Centralized procurement is a demanding approach in terms of human resources, physical infrastructure, management systems, and communication systems.[1] When a Ministry of

Health procurement unit, CMS, parastatal, or ASA directly manages the bidding process, it requires many highly skilled and experienced professionals to ensure that adequate quantities of acceptable-quality products are ordered at competitive prices and delivered on time.[7] Given a global shortage of skilled procurement professionals, it can be difficult to recruit and retain these employees. However, a centralized system does optimize the use of whatever skilled personnel are available by placing them in charge of procurement for entire national health systems.[7]

Ministry of Health procurement systems (including the CMS) often face significant human resources challenges because they operate under the government civil service system and can be viewed as having limited financial or career advancement opportunities, high staff turnover, and political influence over who is hired and fired—especially compared with opportunities that may exist in the commercial sector.[2,6] Theoretically, one of the main advantages of a parastatal or ASA is its ability to hire managers at competitive wages based solely on their expertise and qualifications. An additional advantage is independence from political pressures—although ASAs in practice do not always achieve this level of autonomy.

A centralized procurement unit can cope with skill shortages by choosing less complex procurement mechanisms (for example, avoiding international competitive bidding) or by seeking outside support and resources. In Ghana, for example, the Procurement and Supply Division works with program directors from each vertical program to select products and prepare forecasts. For bids, it relies on the World Bank standard bidding document as a model. This reduces demands on its own personnel and also establishes clear rules and regulations that promote transparency in the bidding process.[2]

Centralized procurement units can also contract out some or all of their functions.[3] For example, they can hire a third-party procurement agent to manage the entire procurement process (see Section F: Procurement Agents). This leaves staff with just two primary responsibilities: forecasting demand and monitoring the performance of the procurement agent.[8] They can also direct shipments to the agent's facilities to shift the problems of physical security of products, limited central storage, and transport. Third-party agents can negotiate prices and sign contracts with suppliers that include delivery to health facilities or district stores. Another variant of this approach is the primary distributor system, in which the procurement unit signs one contract with the supplier and a second contract with a private-sector distributor (the "primary distributor") to store the goods and deliver them to facilities.[1]

g. Vulnerability to Corruption and Political Interference

One of the main drawbacks to the CMS model is the potential for corruption and political interference.[2] Public officials may be tempted by the large amounts of money involved in drug and contraceptive purchases.[4] They may also be subject to political influences or pressures from special interests, such as when senior managers are political appointees or when the agency is required to hire or retain staff members regardless of their qualifications or performance.[1]

Unless there is a robust system to establish and maintain transparency in the procurement process, it can be easy for government procurement officials to make discretionary decisions for their own personal enrichment or to repay political favors.[9] For example, officials may manipulate contract awards to favor specific suppliers, inflate prices to allow individuals to siphon money, buy larger quantities of a drug than are needed, overlook counterfeit drugs, or pay for drugs that are not delivered or that do not meet quality standards.[4]

Compared with a Ministry of Health procurement unit or a CMS model, ASAs and parastatals have the potential to improve transparency, eliminate political interference in procurement decisions, and reduce corruption. Indeed, this is one of the key reasons for governments to shift from one model to the other.[5] However, these organizations do not always possess or practice an adequate level of autonomy.[2] Political influences may shape hiring decisions, or the government may require a parastatal or ASA to distribute drugs without charge or on a credit basis.[1] ASAs generally have greater independence than parastatals and are therefore less prone to political interference.

Regardless of whether a central procurement unit operates as a CMS, parastatal, or ASA, governments must take action to increase transparency and reduce opportunities for corruption. They should enact, implement, and enforce professional guidelines, policies, and practices that encourage ethical behavior and punish individuals and firms for corrupt actions—such as creating open bidding processes with clearly defined procedures for redress.[9] They can also design institutional checks on corruption; for example, by separating the responsibility for procurement decisions from the responsibility for quality control. As detailed in the following case study, the Ministry of Health is responsible for ensuring the quality of health commodities that are procured by *Caja Costarricense del Seguro Social* (or CCSS, an ASA).[5] They can also arrange for good public oversight, including performance monitoring and audits. Audits of Ghana's procurement process, for example, are conducted

annually, and in 2003, the legislature made standard procurement procedures a matter of domestic law.[2]

Case Study: Low Prices but Concerns about Corruption at an ASA in Costa Rica

As of 2009, in Costa Rica, the ASA CCSS is responsible for procuring medicines and contraceptives for the public sector. CCSS procures some contraceptive supplies that are manufactured internationally and imported into Costa Rica by local distributors; it also purchases locally manufactured oral contraceptives at competitive prices. Central procurement has given CCSS greater leverage with commercial suppliers, despite Costa Rica's relatively small market. Bulk purchases have also attracted new suppliers, and thus, increased competition while further reducing prices. For example, several distributors have registered and imported generic injectable contraceptives from Thailand in response to bids from CCSS.

To reduce political pressures and eliminate opportunities for corruption, procurement orders are generated automatically by the central warehouse system based on supply levels and projected consumption. However, corruption scandals have created deep concerns over the efficiency and integrity of the procurement process for health commodities in Costa Rica.

A study of the Costa Rican supply system found that procurement was the stage that was most vulnerable to corruption. There was no documentation on policies, prices paid, or the criteria used to award bids. Because there were no systems to track supplier performance or product quality, suppliers could continue to participate in the competitive bidding system until a legal sentence was issued against them for poor performance. Some public bids were essentially directed to specific suppliers by the wording in the specifications. Suppliers and officials sometimes colluded to create delays in the purchasing cycle so that inventories would be depleted and officials would have to make direct purchases at higher prices than those allowed by competitive bidding. Finally, political pressures sometimes overturned product selection decisions made by procurement officials to increase cost efficiency.

Public debate and pressure have since led to:

1. Wide discussion within government of new laws, decrees, and policies to streamline the procurement process, increase transparency, and improve the quality of products within CCSS.
2. The establishment of a national commission to ensure the quality of health commodities.
3. Separation of the responsibility for QA from procurement by transferring it from CCSS to the Ministry of Health.
4. Requiring that generic commodities be tested for therapeutic equivalence.

Sources: *Using Technology to Fight Corruption in Pharmaceutical Purchasing: Lessons Learned from the Chilean Experience* (Cohen and Montoya, 2001)[4]; *Options for Contraceptive Procurement: Lessons Learned from Latin America and the Caribbean* (Sarley et al., 2006).[5]

h. Funding Issues

A CMS most often operates with funds from central treasury allocations and/or donors, though a CMS can function as a revolving drug fund.[1]

ASAs and parastatals may operate with a variety of different financing mechanisms. Funds may come from centrally controlled government budgets, as in Tanzania; treasury funds allocated to government institutions for drug purchases, as in Uganda; or public-sector revolving drug funds, as in Benin.[1] They may also be allowed to manage donor funds for procurement.[2]

Shifting from a CMS to an ASA or parastatal model cannot solve fundamental problems related to the lack of funding for drugs and contraceptives.[1] If the government retains the ability to require distribution of drugs without charge or on a credit basis (without ensuring payment), the ASA or parastatal will not be able to survive.

i. When is Centralized Procurement Appropriate?

The World Bank recommends that a centralized procurement system be used for large, fixed-quantity purchases of commodities that are on the government's essential medicines list.[7] This makes central procurement especially suitable for contraceptives. However, when small quantities of supplies are needed or emergencies arise, facilities should conduct their own purchasing. This is the approach taken in Zimbabwe, where the CMS procures, stocks, and distributes bulk quantities of high-usage items on the essential medicines list. Other

items are ordered as needed by hospitals based on direct delivery contracts that fix prices based on an annual bid.[1]

2. Decentralized Procurement at the Subnational Level

In recent years, a growing number of countries have decentralized procurement, either as part of broader health-sector reforms or in an effort to better meet local needs through increased local involvement, accountability, and flexibility.[1,2,10] Decentralized procurement pushes varying degrees of responsibility for procurement from the national to the provincial, district, municipal, or even the facility level.[11]

At its most extreme, districts and health facilities may be expected to manage the entire procurement process, from identifying suppliers and negotiating prices to ordering drugs and medical supplies as well as assuring their quality. Frequently, however, decentralized procurement systems do not shift the entire burden of procurement to lower levels. For example, districts and health facilities may be limited to ordering from a national supply authority or from suppliers prequalified by a central office, sometimes at prices also set at the central level; there may be a pooled procurement mechanism; or quality control and auditing functions may be maintained at the central level.[7,10]

Experiences with decentralized pharmaceutical procurement have been mixed, with concerns raised about high prices, poor quality, unreliable supply, and management capacity.[6] This situation has been especially obvious in Brazil, which has changed back and forth between centralized and decentralized models of contraceptive procurement over the past decade: family planning logistics were decentralized in 1997, recentralized in 2000, and then once more decentralized in 2001. As of 2005, the Ministry of Health once again assumed chief responsibility for the procurement and distribution of contraceptives, but some municipalities continue to purchase additional contraceptive methods on their own.[10]

Case Study: Centralized Contraceptive Procurement in Brazil

In Brazil, corruption scandals, health-sector restructuring, and weak technical capacity at various levels of government caused the national procurement strategy to switch back and forth between centralization and decentralization several times between 1997 and 2005. Challenges included lack of infrastructure and procurement capacity at the municipal and state levels, suppliers charging higher prices when municipalities conducted procurement, high tariffs and importation duties, and a restrictive regulatory setting.

The federal government moved to recentralize all contraceptive procurement in 2005, although some municipalities purchase additional methods on their own. Contraceptives are now included on the essential medicines list for basic health care, and the federal government is committed to eventually meeting 100 percent of the entire population's need for a range of contraceptive methods, although traditionally it has not been effective in reaching certain portions of the country.

To accomplish these goals, the federal government is working to strengthen procurement and distribution at every level of government. Currently, the Ministry of Health develops a contraceptive procurement plan, which is reviewed by the Ministry of Planning. Once approved, the General Coordination of Logistics Resources (CGRL) manages the procurement process. CGRL is also responsible for distribution, warehousing management, and, in the case of foreign products, importation and customs clearance.

To promote transparency and prevent corruption, information regarding every step of the procurement process, including the announcement of price registration, details of the bidding documents, and the provisions of the contracts awarded, are made publicly available. The procurement process begins when CGRL issues an invitation for the registration of product prices to potential suppliers. This enables the government to reserve the funds needed for procurement. Once funds are allocated, procurement may follow one of four paths: bids may be open to offers from any interested parties, they may be limited to offers from officially registered firms, they may require an invitation by the administrative authorities, or they may be sent to a public auction.

Sources: *Decentralizing and Integrating Contraceptive Logistics Systems in Latin America and the Caribbean: With Lessons Learned from Asia and Africa* (Beith et al., 2006)[10]; *Options for Contraceptive Procurement: Lessons Learned from Latin America and the Caribbean* (Sarley et al., 2006).[5]

a. Impact on Costs

Certain characteristics of decentralization may tend to control costs. Some believe that cost consciousness is greater at the local level. Local staff responsible for procurement also may be able to better tailor purchases to local needs and thus allocate scarce resources more efficiently. Finally, decentralization may lead to a more equitable distribution of resources, which can benefit marginalized regions and groups while reducing the amount of funds spent elsewhere.[10]

However, decentralizing procurement reduces the size of orders, shifts purchases to local suppliers, and eliminates economies of scale, which usually results in considerably higher

prices.[1,2,5] For example, in Ecuador, 167 health areas (which may comprise departments or large hospitals and health centers) are responsible for procuring their own supplies. Health areas purchase contraceptives annually from a preapproved list of suppliers, a practice that ensures product reliability and quality but does not guarantee prices. While health areas are allowed to procure internationally, they tend to procure locally.[10] The result is contraceptive costs that are far higher than in other Latin American countries. Facilities in Ecuador paid US$2.22 for generic oral contraceptives, while prices elsewhere in the region generally fell within a range of US$0.29 to US$0.33 per cycle. Similarly, Ecuador paid US$2.89 for Copper T-380A intrauterine devices, compared with prices as low as US$0.31 in Chile.[5]

Decentralized systems frequently combine local ordering with some form of centralized price negotiation or purchasing mechanism to retain economies of scale and minimize prices.[5,10] In Guatemala, for example, the procurement of drugs has been decentralized to local health areas. Each year, a central committee negotiates prices with suppliers based on the consolidated needs of the entire public health system. Each health area then places its order directly with suppliers at the negotiated prices and arranges for local delivery of its purchases.[11] When all donations of contraceptive commodities are completely phased out, procurement responsibility for contraceptives may also be decentralized to the local level. The arrangement has resulted in storage and distribution savings for the program.[10]

Similarly, the Ministry of Health system in El Salvador has created a mechanism to consolidate forecasts from its 27 basic integrated health care systems (SIBASIs) and lock in bulk prices for essential medicines. The Essential Drugs Unit at the Ministry of Health tallies up product needs for each SIBASI, negotiates bulk procurements with suppliers, and pools financial resources from each SIBASI to pay for a one-time contract. A similar mechanism is used for contraceptives, except that they are procured from the United Nations Population Fund (UNFPA) rather than local suppliers. The system has contributed to more transparent and more efficient procurement processes as well as substantial cost savings.[11]

b. Impact on Quality Assurance

Decentralization increases the difficulty of ensuring product QA because lower-level staff frequently lack the capacity—including both skills and specialized equipment—to oversee formal quality control procedures and undertake batch testing of contraceptives.[8,11]

To prevent an erosion of product quality, programs may maintain quality control and manufacturing compliance functions at the central level.[10] Indeed, it can be argued that guaranteeing the safety and efficacy of all health commodities circulating in the marketplace,

as well as in the health systems, should be the responsibility of the central government. One common approach is for national authorities to create a list of prequalified suppliers and require local officials to purchase only from those suppliers.[6] This is the way decentralized procurement systems in Bolivia, Colombia, and Ecuador operate.[5,10]

In Bolivia, 314 municipalities individually procure drugs for maternal and child health services. In Colombia, departments, municipal governments, and hospitals directly procure goods and services, including contraceptives. And in Ecuador, procurement is decentralized to 167 health areas. In each country, however, a central office at the Ministry of Health or Ministry of Social Protection prequalifies suppliers based on their contracting history, capacity to deliver needed goods and services, distribution capacity, and working capital. Local procurement officials are required to buy from these suppliers, which provides some assurance of quality and reliability. However, the central authorities do not negotiate prices, so different facilities pay different prices for the same product and prices may fluctuate over time. Because purchases are small in quantity, the system does not realize any economies of scale and prices are high.

Case Study: Pros and Cons of Decentralization in Colombia

After Colombia decentralized its health care system, municipalities assumed responsibility for primary health care and first-level hospitals, while 32 departments assumed responsibility for secondary and tertiary health facilities as well as a major public health campaign. As a result, contraceptive procurement now takes place at every level, including departments, municipalities, and even hospitals if they meet certain criteria.

Decentralization has had both positive and negative effects on family planning. Coverage has increased. Procurement and contracting processes are more flexible, as is the use of resources. However, the system cannot realize any economies of scale for procurement. Product quality also may be less than optimal. Although there are purchasing regulations in place, many hospitals buy locally at the lowest cost without sufficient attention to quality. Finally, poor coordination between the different levels of the system creates considerable opportunity for corruption, including double payments by both the department and municipality.

Source: *Decentralizing and Integrating Contraceptive Logistics Systems in Latin America and the Caribbean: With Lessons Learned from Asia and Africa* (Beith et al., 2006).[10]

c. Impact on Reliability of Supplies

One potential advantage of decentralized procurement is the improvement of the availability and reliability of contraceptive supplies. Decentralized procurement systems often use nearby local suppliers that may include the cost of local delivery in their prices. This can shorten lead times and make deliveries more flexible and efficient. Local control over ordering decisions, shipping schedules, and means of transportation also contribute to more flexible delivery schedules.[11]

Decentralized procurement systems provide local authorities with a greater knowledge of local needs and problems regarding drug and medical supplies and may more easily be held accountable for any problems that arise. As a result, they may be more committed to ensuring the availability of supplies and more willing to explore innovative local solutions to supply problems.[10] For example, when there are stock-outs, health facilities in Ghana can buy supplies at local pharmacies and wholesalers to maintain availability of key products, while municipalities in Bolivia have explored arrangements with other municipalities, nongovernmental organizations, and private providers.[2,10]

The power of local oversight to improve the availability of health products can best be seen in Vietnam, where the Ministry of Health and the United Nations Children's Fund provided seed stock and training for revolving drug funds at the community level. Since their establishment in 1994, more than 80 percent of the drug funds have operated sustainably, and affordable, good-quality drugs are now routinely available at most health centers.[12] Decisions regarding ordering, procurement, and the sale of drugs have been decentralized to the community and facility levels, with committees of trained local people providing co-management and oversight. The participation of these local committees has been crucial to the success of the funds; funds lacking this kind of local involvement have become decapitalized or exclusively profit oriented. Greater availability of drugs at the health centers has increased demand and sales volume. This, along with cash payments to suppliers (in contrast to the slow and bureaucratic central government reimbursement system), has provided an incentive for private vendors to enter the market and compete with the official government supplier.

d. Impact on Management

The greatest challenge in decentralizing procurement systems is providing for adequate human resources capacity in each district or health facility. Because procurement professionals are in short supply, there are usually few or no staff members with procurement skills or experience at lower levels of the health system.[2,7] If decentralized

systems are to succeed, countries must gradually develop capacity at lower levels before devolving the responsibility for procurement. It is essential to:

- Ensure that there are personnel available at the local level to take on these new roles and responsibilities.
- Explicitly delegate procurement authority, functions, and responsibilities to local personnel as part of their position descriptions.
- Invest in the training and supervision needed for local personnel to master essential procurement and supply chain knowledge and skills.
- Supply the information systems and other resources needed to support their new functions.[10,11]

In essence, a decentralized approach means that health systems are duplicating existing procurement skills at the central level many times over, which is inherently inefficient and costly.[8] Health systems can reduce the management burden of procurement on districts and facilities by centralizing some functions, such as the negotiation of bids and prices.[2]

Frequently, decentralization has disrupted contraceptive procurement and logistics because there was insufficient action taken to develop the procurement capacity of local staff.[11] In Brazil, for example, the availability of contraceptives suffered when procurement was decentralized to municipalities without proper local capacity-building, and the family planning supply chain was recentralized.[11] Similarly, in Mexico, decentralization led to some regions not ordering enough contraceptives, which produced stock-outs at many levels. In response, the Ministry of Health required states to reserve at least 10 percent of their budget for contraceptive procurement and also gave states the option to order contraceptives directly from the central level through a pooled procurement mechanism.[10]

Less obvious is the need to reorient procurement officials at the central level to play a new and different role, that is, to guide local staff who are assuming responsibility for procurement by developing regulations, norms, protocols, and procedures.[10,11] Central procurement officials should also be responsible for monitoring local performance and making sure local procurement officers adhere to good procurement practice. Otherwise, a decentralized system may not meet public health objectives and may waste scarce funds.[6]

In Ecuador, for example, decentralized procurement by health areas has been hampered by the lack of guidance from above. There is no standardized system that clearly establishes the frequency of contraceptive procurement, logistics training for local staff members is limited, and there are no procedural manuals or supervisory visits addressing logistics issues. One

key recommendation for improving the system is to strengthen the role of the central level first in developing and implementing norms, procedures, and guidelines, and then in making sure that they are followed at the local level.[10]

Center-led procurement, which is an innovative, flexible procurement model developed by the business world, provides a useful model here.[13] Center-led procurement encourages companies to use a mix of different purchasing models and mechanisms—ranging from centralized sourcing to decentralized buying—depending on what is being bought, who needs it, and where it will be used. However, the central purchasing department is expected to contribute its expertise to every transaction and to structure and guide all buying processes. For example, central purchasing might draft a set of best practices for procuring specific goods or services and disseminate them to local units conducting decentralized procurement. The analysis would draw attention to potential hidden costs and point out savings drivers.

e. Impact on Corruption and Political Interference

Decentralization can have contrary effects on corruption and political interference. On the one hand, the smaller amounts of money involved in each transaction may reduce the incentive for corrupt behavior.[4] Close local oversight may improve transparency and accountability.[10] Increasing the number of people involved in procurement may also make large-scale corruption more difficult. In Thailand, for example, centralizing procurement from individual hospitals and health centers to provincial health officers facilitated wide-scale corruption, because politicians found it easier to pressure a smaller number of officials with authority over procurements to direct purchases to preferred companies.[14]

On the other hand, decentralization actually increases the opportunities for corruption, albeit on a smaller scale, because it increases the sheer number of procurement transactions taking place.[4] Larger numbers of transactions and procurement decision-makers also make it more difficult to enforce rules and regulations for transparent procurement practices.[1,2] A short-lived anticorruption campaign in Buenos Aires, Argentina, in the mid 1990s demonstrates that corruption exists in decentralized systems. The Health Secretariat began collecting and compiling data on the supplies ordered and prices paid by each of the 33 public hospitals that conducted procurement. They shared that information with the hospitals, highlighting the high and low prices. Prices fell almost 15 percent after monitoring began, despite the fact that there were no prizes or punishments attached. After a few months, when anticorruption rhetoric waned, prices began to rise again, beginning with hospitals that had the lowest wages for procurement officers.[15]

f. Impact on Funding

If procurement is decentralized, then financial resources must follow. When local authorities are given responsibility for procurement without an adequate budget, decentralization becomes an abandonment of responsibility.[1]

g. When is Decentralized Procurement Appropriate?

Decentralized procurement is most appropriate for emergencies, small quantities, items that are not on national essential medicines lists, and products that are available from a number of local suppliers. Estimated quantity supply contracts are a good fit for decentralized systems. Under these contracts, local authorities place orders as needed at prenegotiated prices that are based on estimated order volumes.[7]

Case Study: The Impact of Decentralization in Mexico

In Mexico, contraceptive procurement was decentralized to the state level almost immediately after the United States Agency for International Development phased out contraceptive donations in 1996. Planning was poor, however, so most states were unprepared and unfamiliar with the processes for projecting demand, planning procurements, and budgeting for their contraceptive needs. The result was frequent stock-outs and a major rupture in the supply of contraceptives, despite the maturity of the program, a supportive environment, and relatively good technical and financial capacity.

In response, Mexico's *Secretaría de Salud* (SSA) established a coordinated contraceptive procurement mechanism at the central level. The SSA began making annual contraceptive procurements through UNFPA, which gave states access to international prices and achieved significant cost savings. In 2002, the states saved approximately US$3.9 million compared with what they would have paid on the commercial market. However, fewer than half of Mexico's 32 states have participated in the coordinated procurement process because of delays in delivery, stringent quality control measures for imported products, UNFPA's requirement of full payment in advance, and UNFPA's reluctance to issue fiscal receipts required by most federal and state entities.

Mexico's other major public health institution, the *Instituto Mexicano del Seguro Social* (IMSS), declined to join in central procurement from UNFPA. IMSS, which had been procuring contraceptives from commercial suppliers since the early 1990s, was afraid the length of the UNFPA procurement process could create stock-outs and was unsure of

the real cost savings since UNFPA prices do not include distribution costs. IMSS had continued to procure its contraceptives through commercial suppliers, but it has had to pay significantly higher prices than SSA and has also come under pressure to improve the transparency of its procurement processes.

Source: *Options for Contraceptive Procurement: Lessons Learned from Latin America and the Caribbean* (Sarley et al., 2006).[5]

In summary, each model has effects, disadvantages, and advantages, as shown in Tables 1 and 2.

Table 1. Impact of Different Procurement Models

Procurement Model	Effect on Prices	Quality Safeguards	Lead Times	Management Capacity Required	Vulnerability to Corruption and Political Interference	Appropriate For?
Centralized	Positive	Potentially strong	Moderate	Strong	High	-Large orders -Items on national essential medicines lists
Decentralized	Negative	Weak	Short	Strong	Moderate to high	-Small quantities -Emergency items on essential medicines lists

Table 2. Key Advantages and Disadvantages of Various Models

Procurement Model or Mechanism	Advantages	Disadvantages
Central medical stores	- Economies of scale reduce prices and administrative costs - Optimizes use of scarce procurement professionals	- Highly vulnerable to political interference - Civil service employment conditions make it difficult to hire and retain skilled staff and limit accountability
Parastatals and ASAs	- Economies of scale reduce prices and administrative costs - Optimizes use of scarce procurement professionals - Promotes commercial business practices	- Somewhat vulnerable to political interference - Potential conflict between public health and commercial goals
Decentralized	- Local control makes system more responsive to local needs and more accountable to clients - Shorter lead times and more flexible deliveries	- Small orders mean higher prices - Duplication of effort increases administrative costs - Need to create procurement capacity at lower levels - Difficult to enforce procurement regulations

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H. Product Quality Assurance

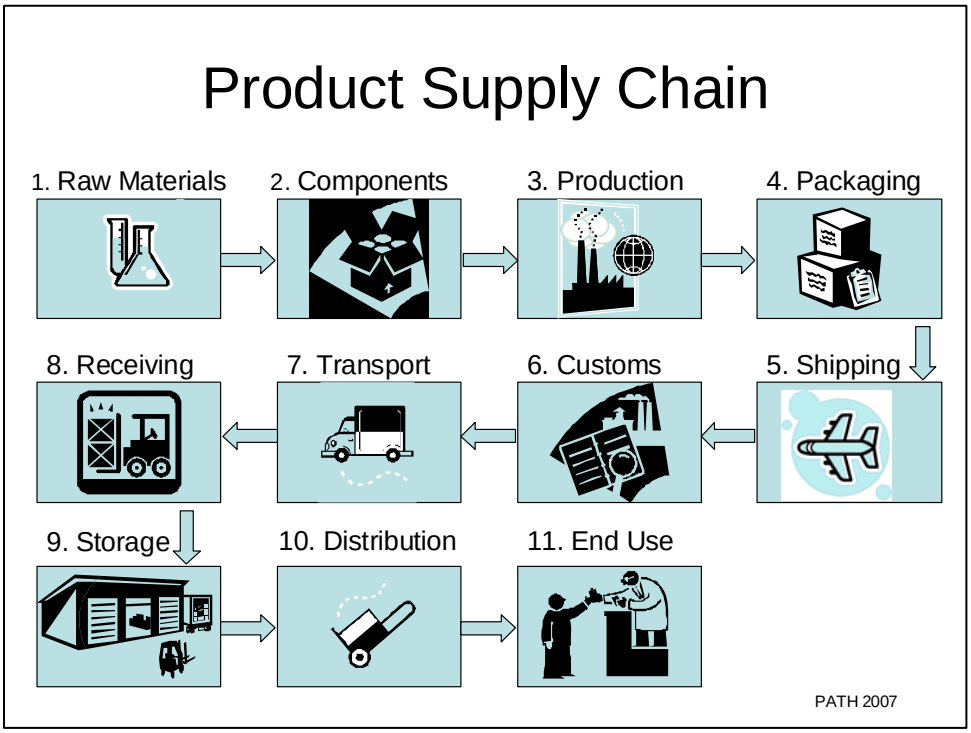
Product quality assurance (QA) is the sum of all activities and responsibilities intended to ensure that a product complies with the applicable quality specifications. The importance of product QA cannot be understated; poor-quality drugs and medical devices can negatively impact the lives of end users and erode consumer confidence in public health services. The lack of a QA system leads to poor-quality medicines entering the public and private health care market, which contributes to the proliferation of diseases, especially those that become resistant to traditional first-line medicines.

A QA system can be divided into three parts: ensuring products meet current standards for quality, verifying shipped products meet specifications, and monitoring and maintaining quality once products are received until they are consumed by the end user. Critical components of a QA system at the manufacturer level are current good manufacturing practices (cGMPs) and quality control procedures.

Quality control procedures verify that the product is of acceptable quality. The key players involved in the supply and quality control of products include the procurement unit, national drug and medical device regulatory authority, raw materials suppliers, manufacturers, logistics systems personnel, the service provider, and end users. Of all these key players, manufacturers are primarily responsible for the quality of the drugs and medical devices.

1. Quality in the Product Supply Chain

The graphic below provides a visual overview of the key activities that occur in the standard product supply chain. The overall lifecycle of medicines and medical devices has several points at which QA needs to be implemented and verified through checkpoints, from manufacturing to end use.



Important points to remember about the product supply chain are as follows:

1. **Raw materials:** Use of poor-quality or counterfeit raw materials can impact component fabrication and pose a risk to quality.
2. **Components:** Use of poor-quality or substandard components can pose a risk to quality in the production of end products.
3. **Production:** The absence of or problems with active ingredients, such as cross-contamination of other products made on the same manufacturing line, and nonadherence to cGMPs can lead to a poor-quality product.
4. **Packaging:** It is important that the packing materials are not substandard because they will not adequately protect the product. Additionally, the product should be labeled properly on the primary package for easy and accurate identification.
5. **Shipping:** Knowing product requirements and preparing accurate and comprehensive shipping requirements for the product are imperative for maintaining product quality during transit. An example is temperature-sensitive products like vaccines.
6. **Customs:** To avoid delays in clearing customs, products must be registered and all required documentation must be submitted on time. Product registration and customs approval of such is another verification of QA.

7. **Transport:** Providing adequate transport, in a timely manner, ensures the delivery of the product on time and within the conditions required (e.g., refrigerated).
8. **Receiving:** Upon receipt, all products should be inspected for visual damage and the receipt, condition, and quantity properly recorded in the logbook. Procurement should be notified of the arrival of damaged products. More information about visual inspection can be found in Section I: Product Inspection and Testing.
9. **Storage:** The environment of the warehouse should be regulated to take into consideration the impacts on products of temperature, moisture, and exposure to direct sunlight. Additionally, the warehouse should be well organized, so products can be easily located and do not become damaged, and expiration dates can be monitored.
10. **Distribution:** The considerations for QA as the product is distributed from the central warehouse to the end user are proper loading and securing of the shipment, temperature controls (when required), and commodity security.
11. **End use:** It is important that the dispenser is knowledgeable about the product in order to provide the end user with instructions on proper use. Additionally, the storage requirements of the product need to be followed by the dispenser and patient to maintain QA.

2. Roles and Responsibilities

No individual agency bears the sole responsibility for assuring product quality through the lifecycle of a product. Quality is assured by collective and responsible action from each player throughout the supply chain. The roles and responsibilities of each of these players to ensure product quality are described below.

a. Role of the Procurement Unit

The critical role of the procurement unit in obtaining quality products cannot be overemphasized. The procurement agency must have procedures in place to ensure that the products being procured are safe and effective and that it has maximized supplier selection and assessed its own capacity to judge these requirements. The procurement agency must maintain a comprehensive documentation infrastructure that includes policies, guidelines, standards, manuals, procedures, records, and related documents.

The recommended process for ensuring quality products is to purchase from World Health Organization (WHO)-prequalified manufacturers (see Section E: Prequalification). However, when this is not possible, then the purchaser is advised to take the following steps:

1. Know the best available product standards. Check with the local regulatory authority to identify registered products and national standards. If these are not available, then check with other regulatory authorities or international standards bodies, such as the International Organization for Standardization (ISO) and pharmacopoeias. Ensure that the products specified comply with country legislation on registration licensing status and patent registration or restrictions.

2. Know the marketplace and the available manufacturers. The purchaser must ensure that the product can be traced to the finished product manufacturer, and the manufacturer can trace the product ingredients to their producers. Understand the capacity of the supplier's plant(s). Evaluate the qualifications of key production and quality control personnel. Investigate how the supplier is regarded by knowledgeable physicians and pharmacists. Review any internationally recognized certificates that the manufacturer holds (e.g., ISO). Review any information available from public sources (such as newspapers or trade journals) concerning the supplier's performance locally or in other countries.

   Check if the supplier is registered in the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S, http://www.picscheme.org) or International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH, http://www.ich.org) as a member country, if the product is registered for export only, and if the product is registered in the country of the purchaser. (See Section I: Product Inspection and Testing and Section K: Regulatory Authorities for more information on the PIC/S and ICH.) Contact the national regulatory authority to establish what types of inspections are performed at the manufacturing site and what medicines or medical devices are quality control tested for analytical verification of quality (levels and types of inspections, if any, can vary from country to country). Review the results of the most recent inspections and inquire about recall history. Review certification documents that are available from the regulatory authority concerning the supplier's status and compliance with cGMPs.

   Buyers with pharmaceutical staff trained in cGMP inspection or that hire a consultant with this expertise may perform their own inspections of manufacturers that are potential suppliers if funds are available to do so. In any case, the purchaser

should always reserve the right to inspect the manufacturing facility. Request references from the supplier and check them, investigating any concerns or episodes of quality problems.

3. Work with the pharmacy staff to develop and articulate appropriate quality indicators and quality conformance requirements that will be used as part of the product and contract specifications. One possible requirement may be to review manufacturer documents, such as batch certificates of analysis, sterility, or others as applicable. Another may be to conduct preshipment testing by an independent, credible international laboratory (also see Module 9: Contract Performance and Monitoring). Include penalties in the contract for failure to comply with stated quality indicators.
4. Ensure that the product specifications are brand neutral. Beware of specifications that pertain to only one manufacturer's product.
5. Upon arrival of the goods, the procurement unit should follow up with the supplier on any issues regarding the visual inspection of the products and/or the goods and quantities delivered.

b. Role of the National Drug and Medical Device Regulatory Authority

The establishment of a national drug and medical device regulatory authority is an important element of a national drug policy, particularly in developing countries, since it provides the basis for product licensing, which is intended to ensure the quality of both imported and domestically produced products. A comprehensive registration or licensing system should include mechanisms for independent product evaluation, including inspection and monitoring of manufacturing facilities, as well as testing and inspection of finished products. Drug regulatory authorities should have authority to recommend and enforce corrective actions when necessary. It is advised that national regulatory authorities be responsible for monitoring the quality and safety of medicines to prevent harmful, substandard, and counterfeit medicines from reaching the public. This monitoring is referred to as post-market surveillance and involves selecting random samples from the market and testing them for efficacy and confirmation of product registration. National regulatory authorities should also monitor adverse drug reactions, disseminate medicine and poison information, and implement and update medicine regulations.

The degree of development of the drug regulatory authority varies considerably among countries, ranging from those with limited capacity (i.e., no up-to-date legislation or regulation) to those considered stringent regulatory authorities with comprehensive drug

regulatory capacity (including, for example, product registration, licensing for manufacture or distribution, and a full range of quality control testing). For more information about countries with stringent regulatory authorities, see Section K: Regulatory Authorities. These differences notwithstanding, the standard of control varies from country to country and even among comparable systems. In some exporting countries, drugs are registered and sold freely but not rigorously evaluated for efficacy. In other countries, manufacturers may produce exclusively for export; the exporting country's drug regulatory authority may not closely scrutinize these manufacturing facilities. Procurement offices still need to request certificates from the drug regulatory authority of the exporting country as recommended by WHO.

c. Roles of the Raw Materials Suppliers and the Manufacturer

Raw materials suppliers are responsible for identifying manufacturing requirements and control specifications to ensure that products can consistently be produced in accordance with these requirements. A supplier must adhere to international pharmacopoeia standards, and must also conduct the necessary tests and sampling to demonstrate that a product is safe, effective for its intended use, and of good quality. Additionally, a raw materials supplier must certify the safety, efficacy, and stability of the finished raw materials and maintain the necessary drug master files and monographs of the active pharmaceutical ingredients.

The manufacturer is responsible for ensuring that pharmaceutical products are fit for their intended use and comply with applicable national or international standards and purchase contract specifications. It is the manufacturer's further responsibility not to place users at risk due to inadequate safety, quality, or efficacy. Throughout the production process, manufacturers must adhere to cGMPs. As part of cGMPs, manufacturers should validate all raw materials and suppliers to ensure that starting materials meet production specifications. In particular, a manufacturer should have an independent quality control unit that monitors the quality of incoming materials, the quality of the product at key stages in the production process, and finished products. Manufacturers also must monitor product stability to ensure that products do not deteriorate before the marked expiry date.

d. Role of the Logistics System

A reproductive health program's logistics management information system plays the primary role in ensuring product quality from the time the product clears customs until the time it reaches the user. The logistics system is responsible for ensuring that products are transported and stored adequately and that practices such as "first expiry, first out" are routinely used in distribution. Products need to be stored in such a way that their quality

and integrity are preserved and that batch traceability is maintained. All logistics systems should have mechanisms for monitoring product quality upon receipt and at regular intervals during storage, and for documenting and reporting results.

e. Roles of the Service Provider and End User

Service providers and users also play important roles in ensuring product quality and effectiveness. Providers should store products according to the manufacturer's directions and should check the expiry date, the integrity of the packaging, and any other signs of possible deterioration of the product before distribution to users. Users should also be made familiar with the expiration date and package integrity of all products before use. Users should report any adverse reactions to the provider, who in turn should report them to the logistics manager, clinical manager of the program, or other individuals, depending on the nature of the complaint and the established reporting procedures.

3. Quality Assurance Standards and Norms

To help the above key players better manage their processes for ensuring quality and build on existing national standards, several international standards and norms have been developed. These standards and norms establish specific procedures and practices that are designed to support a consistent approach to implementing operational activities so that inherent risks to product quality can be mitigated.

- **Current good manufacturing practices** is a term that is recognized worldwide and refers to quality systems regulation. cGMPs are followed by manufacturers for the control and management of the quality control of foods, pharmaceutical products, and medical devices. Products must meet specific requirements for identity, strength, purity, quality, safety, and efficacy.
- **The Global Harmonization Task Force** (GHTF) is a voluntary group of representatives from national medical device regulatory authorities and the regulated industry in Australia, Canada, the European Union, Japan, and the United States. In 2006, membership expanded to include three liaison body members: the Asian Harmonization Working Party, the ISO, and the International Electrotechnical Commission. The purpose of the GHTF is to encourage convergence in regulatory practices related to ensuring the safety, effectiveness/performance, and quality of medical devices; promote technological innovation; and facilitate international trade. The primary way in which this purpose is accomplished is via the publication and dissemination of harmonized documents on basic regulatory practices.

- **Good laboratory practices** embody a set of principles that provide a framework within which laboratory studies are planned, performed, monitored, recorded, reported, and archived.
- **Good dispensing practices** confirm the authenticity of the product, inspect the package and product, and ensure storage of the product under required conditions.
- **The International Standards Organization** develops standards that provide a broad umbrella for quality systems as well as specific product standards. For instance, ISO 9001 outlines criteria for a quality management system, and ISO 13485 is a standard specifically for systems controlling the manufacture of high-quality medical devices. ISO standards also call out product-specific standards, such as ISO 4074, which specifies male condom requirements and testing standards.
- **The CE mark** is a mandatory European marking for certain product groups to indicate conformity with the essential health and safety requirements set out in European Directives for the European Economic Area. To permit the use of a CE mark on a product, proof that the item meets the relevant requirements must be documented. By affixing the CE mark, the manufacturer, or in certain cases, another legal person responsible for the product, asserts that the item meets all the essential "health and safety" requirements of the relevant European Directive(s) that provide for the CE mark.
- **WHO Department of Medicines Policy and Standards** is the lead department in WHO for medicines policies, norms, and standards. The department develops, validates, disseminates, and promotes global policy guidance, norms, and standards on pharmaceuticals, including essential medicines. It also conducts the Prequalification of Medicines Programme for manufacturers of medicines that treat HIV/AIDS, malaria, tuberculosis, and reproductive health. The Prequalification Programme also addresses certain devices and equipment. See Section E: Prequalification for more information.

Resources

***Ensuring the Quality of Medicines in Resource-Limited Countries: An Operational Guide* (United States Pharmacopeia Drug Quality and Information Program and collaborators, 2007)**

This guide provides a sequential overview of major topics that need to be considered to properly ensure the quality of medicines in resource-limited settings. It contains detailed explanations of fundamental concepts, principles, definitions and use of terms, checklists, and practical examples to implement effective changes in QA. (The terms medicine, drug, drug product, pharmaceutical, and pharmaceutical product are used interchangeably.)

http://www.usp.org/pdf/EN/dqi/ensuringQualityOperationalGuide.pdf

***Managing Drug Supply: The Selection, Procurement, Distribution, and Use of Pharmaceuticals* (2nd Edition) (Management Sciences for Health/WHO, 1997)**

This book describes how to manage essential medicines, especially in developing countries. It is based on three fundamental beliefs: (1) Essential medicines are critical to the success of health programs, (2) improving the management of pharmaceutical supply is a high-leverage opportunity to improve health services, and (3) knowledge and experience concerning effective pharmaceutical management are spreading rapidly worldwide.

Available for purchase at: http://www.msh.org/resource-center/ebookstore/product.cfm?p=43

***Requirements for the Quality Assurance of Hormonal Contraceptives* (WHO, 1995)**

This document summarizes the basic systems required to ensure the quality of imported and domestically manufactured oral and injectable contraceptives. It provides information on national and international regulatory mechanisms that can help to ensure the production and procurement of good-quality products and suggests a systematic approach to monitoring the quality of oral and injectable contraceptives once they leave the manufacturer.

http://www.who.int/reproductivehealth/publications/family_planning/HRP_ITT_95_1/en/index.html

WHO Prequalification Programme

This website details all major topic areas for the WHO Prequalification of Medicines Programme. In close cooperation with national regulatory agencies and partner organizations, the Prequalification Programme aims to make high-quality priority medicines

available for the benefit of those in need. This is achieved through its evaluation and inspection activities, and by building national capacity for sustainable manufacturing and monitoring of medicines.

http://www.who.int/prequal/

International Organization for Standardization

The ISO is a nongovernmental network of the national standards institutes of 162 countries, which develops and publishes international standards.

http://www.iso.org/iso/home.htm

I. Product Inspection and Testing

One way to assess the quality of a product is to inspect and test it prior to final acceptance. It is important to only test against criteria identified in the specifications defined in the contract documents. Testing helps to reduce the amount of substandard and counterfeit products entering the health care system. There are three basic levels of product compliance review that a purchaser can implement: document review, visual inspection of product, and laboratory or physical testing of product. At a minimum, all shipments should be subject to document review and visual inspection to verify compliance with contract specifications and order completeness, and to identify any abnormalities with the shipment (damage, leakage, incorrect markings, etc.). The next level for assessing the quality of a product is provided by laboratory (physical) testing; however, many countries do not have a fully functional national medicines quality control laboratory due to the level of technical expertise and financial resources required to operate and maintain such a facility. In those countries without a national laboratory, there is the option of contracting a private laboratory in-country or in another country.

A purchaser helps ensure product quality by implementing either pre- or post-shipment inspection. It is often in the purchaser's best interest to conduct a preshipment inspection, as this can prevent the cost and burden of returning the products and obtaining replacements. More information on preshipment inspection can be found in Module 9: Contract Performance and Monitoring, Section E. The purchaser reserves the right to conduct preshipment or post-shipment inspection by including the requirement in the bidding documents and the contract issued to the supplier. The three levels of product compliance review are discussed below.

1. Document Review

The purchaser should arrange to have documentation submitted by the supplier, such as a Certificate of Analysis and certification of compliance with current good manufacturing practices (cGMPs), reviewed by qualified personnel to confirm that the required tests were satisfactorily conducted in compliance with cGMPs. Shipping documents should be reviewed to ensure the shipment is in compliance with contract and shipping requirements.

2. Visual Inspection

Visual inspection can be conducted pre- or post-shipment to examine a product and various aspects of its packaging, labeling, and markings. It is important that visual inspection be

carried out in a systematic manner according to specified criteria by trained personnel. During a visual inspection, a representative sample of the product is compared to what has been specified in the contract. Products that differ from the contract requirements are considered to be nonconforming or defective. Defects can range from minor to critical. The decision to accept or reject a batch (production lot) should be based on a comparison of the inspection results to the acceptable quality limit specified in the contract. A simple visual inspection guideline is provided in Module 2: Specifications (Exhibits 2-1 and 2-2). Visual inspection *can* provide information on whether the:

- Correct product was received.
- Product is in good physical condition and meets relevant contract terms and conditions.
- Packaging is intact.
- Product is adequately labeled.
- Product is supplied in the specified quantities.
- Expiration date is valid.

Visual inspection *cannot* provide information on:

- Whether the product contains the specified amounts of ingredients.
- Potency level.
- Product sterility (for injectable contraceptives and implants, for example).

a. Visual Inspection: Classification of Defects

Visual inspection will likely reveal a variety of deviations from the contract technical specifications. Some of these will be of enough concern to warrant rejection of the product being inspected, while others may affect less important quality characteristics. The following classifications of defects can be used for visual inspection:

- A **minor defect** is unlikely to affect the usability of the product, but represents a departure from specifications—for instance, improper carton flap closure.
- A **major defect** may make the product more difficult to use, but does not have a safety or efficacy risk—for instance, missing unit packages, incomplete labeling on outer cartons, or damaged cartons.

- A **critical defect** is defined as a defect which, according to experience and professional criteria, makes the product potentially dangerous or not viable for its intended use—for instance, missing tablets or missing lot number on unit package.

The programmatic response to defects identified during visual inspection will vary depending on the reason for the inspection.

The classification of critical or major visual defects often implies that further action must be taken. For example, if cracked oral contraceptives are noted in a visual inspection, the next step may be to select a sample for laboratory testing. If laboratory tests reveal that the chemical composition of the pills meets requirements, the program may make the decision to distribute the pills. The program needs to consider the severity of the defects, the extent to which the defects will affect normal use, the existence of replacement stock, or the costs to the program of destroying the products and replacing them. Additionally, if the defect affects only a small portion of the lot or shipment, the program may decide to sort out the defective products and distribute the remaining products, assuming that they are otherwise in good condition and meet quality requirements. The procurement unit needs to bring all defects to the attention of the supplier, regardless of the severity. In the case of minor defects, this may be the only follow-up action required. In the case of major or critical defects, the supplier shall be held responsible according to the terms and conditions of the contract.

3. Laboratory Testing

Contract terms and conditions should state the analytical tests and requirements against which the product may be evaluated before the contract is signed. Although laboratory analysis of pharmaceuticals is generally not necessary when dealing with a known supplier, it may be warranted in special cases, such as when dealing with a new supplier, when product quality is questioned after visual inspection (see section below), or when drug counterfeiting is suspected.

As a general rule, the first three shipments from a new manufacturer should be sampled for testing against the requirements laid out in the contract. If all of the lots tested meet the specified standards, testing of remaining or future lots is not necessary. Suppliers with unacceptable failure rates are dropped from future bids. If there is reason to suspect a quality problem, samples from each subsequent shipment should be tested. Even though laboratory analysis may not be carried out on a routine basis, a provision for laboratory testing should be included in all contracts, to be exercised at the discretion of the

purchaser. The supplier should not be expected to comply with tests not specified in the contract.

The national regulatory authority may require that products meet the analytical test requirements specified in the national pharmacopoeia or an internationally recognized pharmacopoeia. If pharmacopoeia testing requirements exist, they should be stated in the contract terms and conditions. If pharmacopoeia testing requirements do not exist or if the national pharmacopoeia does not specify tests, an appropriate internationally recognized pharmacopoeial standard should be stated in the terms and conditions. The British, Japanese, and United States Pharmacopoeias; the European Pharmacopoeia; and the International Pharmacopoeia (produced by the World Health Organization [WHO]) are the most widely used. The major pharmacopoeias include specifications for raw materials and finished products in their finished dosage form and are organized by generic name (international nonproprietary name), not brand name. The purchaser may also wish to specify that the product meet certain nonpharmacopoeial test requirements; an example would be package seal integrity or particle size (for injectable preparations).

Basic tests for different contraceptives are described below.

For injectable contraceptives:

- Identification of active pharmaceutical ingredient (API).
- Assay content of API.
- Content uniformity (for suspensions).
- Filling volume.
- Integrity of filled containers.
- Particle size (for suspensions).
- pH level.
- Pyrogens.
- Sterility—no microorganisms detected.
- Particulate matter.

For tablets:

- Identification of API.
- Assay content of API.

- Content uniformity.
- Disintegration—determines solid dosage form will disintegrate.
- Dissolution—medicine will dissolve in the body.

For condoms:

- Performance requirements:
  - Burst volume before and after oven conditioning.
  - Burst pressure before and after oven conditioning.
  - Freedom from holes.
  - Visible defects.
  - Package integrity.
- Design requirements:
  - Shape and texture.
  - Integral bead.
  - Color.
  - Scents and flavoring.
  - Width, length, and thickness.
  - Lubricant quality.

For diaphragms:

- Dimensional inspection.
- Membrane thickness.
- Tensile and elongation of the membrane.
- Compression resistance of spring.
- Twisting during compression.
- Accelerated aging and fatigue resistance.

For intrauterine devices:

- Sterility.
- Package burst strength.

The procurement unit should rely on an expert technical committee to advise on testing issues, interpretation of test results, and resulting decisions. Committee members could include individuals from the drug regulatory authority and clinical experts from within the reproductive health program.

4. Testing Laboratories

Many countries do not have local testing laboratories that can perform all of the tests that may be required. For example, condom testing requires specialized equipment compared to drug testing. WHO has developed practical guidelines for establishing small- and medium-sized testing facilities.[†††††] However, it may not be cost effective for some countries to establish a sophisticated national drug control laboratory for a number of reasons, including:

- Low projected volume of work, making it difficult to maintain staff skill levels, equipment calibration, and accreditation.
- Insufficient financial resources for land purchase, facility construction, testing equipment, furniture, supplies, equipment maintenance, salaries, training, and other operating costs.
- Lack of trained personnel, such as microbiologists, pharmacologists, laboratory technicians, and animal caretakers.
- Lack of local capacity for maintenance and repair of equipment, difficulty in obtaining spare parts, and irregular or unstable power supply.

The most common problem in maintaining a competent testing laboratory is low projected volume of work, since technician skills and equipment efficiency can decline seriously when not frequently or routinely applied. One solution is to use contracted testing services. Contracting with an independent agency or national laboratory to perform visual inspection and/or analytical testing can be useful when a neutral, third-party assessment is needed or when the purchaser is limited in its ability to monitor product quality or contract compliance when, for example, the supplier is in another country. Independent testing laboratories can provide a wide variety of services, ranging from conducting laboratory tests and onsite sampling and inspections to facilitating customs and shipping procedures. When using an independent company or national laboratory, the purchaser should retain complete control over the arrangements for inspection and testing, including contracting for the

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[†††††] **Good Laboratory Practices in Governmental Drug Control Laboratories. In: *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirtieth Report.* WHO Technical Report Series No. 748. Geneva: World Health Organization; 1987: 20–39. Available at: http://whqlibdoc.who.int/trs/WHO_TRS_748.pdf.**

services. It is the responsibility of the purchaser to develop the scope of work and establish the parameters within which the inspection and testing services are to be accomplished. The scope of work needs to be carefully defined by the purchaser and agreed upon by the testing agency. The contract should clearly establish such details as:

- When and where the inspection and/or testing should take place.
- The time frame for accomplishing the work.
- What sampling protocol should be followed.
- Who is responsible for pulling product samples.
- The standards to which materials and products should be tested.
- The agreed-upon payment for requested services.

A critical element of working with a testing service is understanding that the service will not advise on actions to be taken. The testing service will only provide results against set parameters. The procurement unit, in consultation with its quality assurance experts, still needs to make a call as to whether the results show serious enough deficiencies to stop distribution.

The costs for independent testing services will vary, depending on the requirements of the particular contract. All costs need to be outlined in a contract and agreed upon before the company will carry out the requested work.

WHO has recommended norms and standards for quality control laboratories and has a prequalification process for such laboratories. A list of prequalified laboratories and more information about the laboratory prequalification program can be found on the WHO Prequalification of Medicines Programme website listed in Resources below. *The Male Latex Condom: Specification and Guidelines for Condom Procurement* (WHO, 2003) includes a list of condom testing laboratories (see Resources). The condom testing laboratories are included in this document for informational purposes only.

Resources

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http://www.who.int/prequal/

***The Male Latex Condom: Specification and Guidelines for Condom Procurement* (WHO/United Nations Population Fund [UNFPA]/Joint United Nations Programme on HIV/AIDS [UNAIDS], 2003)**

This document developed by WHO is designed to provide a set of purchase specifications and procurement guidelines that ensure the highest level of quality assurance for condoms consistent with high-volume purchases, the needs of different populations, harsh environmental conditions, and the probability of less-than-ideal storage conditions. It recommends the prequalification of primary manufacturers and lot-by-lot compliance testing prior to shipping condoms from the country of manufacture. The document also provides a list of manufacturers and testing laboratories *for informational purposes only*. Appearance on this list does not imply endorsement by WHO, UNFPA, or UNAIDS.

http://www.who.int/reproductivehealth/publications/family_planning/9241591277/en/

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J. Recordkeeping

Good recordkeeping is a critical supporting component of a transparent and fair procurement process. This activity involves setting up an efficient and dependable information management system that not only maintains records of important bidding and contract documents but also provides accurate information on the current status of individual bidding processes.

Comprehensive procurement documentation provides procurement organizations with the historical data required to defend procurement actions taken, and can assist in informing future procurement actions. Effectively run procurement organizations create recordkeeping processes to ensure that key records are kept to document the procurement process as it takes place, reducing the efforts required to assemble the records at the end of the procurement process. Recordkeeping, however, is an area frequently overlooked with regard to staff time and financial resources allocated to producing adequate and useful procurement records.

1. Purpose of Recordkeeping

The main purpose of maintaining procurement records is to provide historical and legally binding information in easy-to-read, sequentially organized procurement files so that procurement actions and decisions can be understood.

Effective procurement documentation should:

- **Provide a permanent historical record of the procurement:** Documents created during the procurement process create a historical record of actions taken and will serve to provide a written record that can be drawn on in the future. Once the documents are assembled in a single set of files, they are the main source of data and the official record of the particular procurement actions.
- **Provide a legal record of procurement actions taken:** Procurement documents are the official and legal record of actions taken. It is critical that the procurement documentation capture all of the relevant information of the procurement. These records may be required in defense of any legal protests against the procuring organization, such as bid protests and contract disputes.
- **Explain the process and decisions made in a sequential manner:** When procurement documentation is assembled in the sequence that it is created, it is

easy to understand the history. Assembling the procurement records from start through finish as the procurement process proceeds makes the job of documenting the procurement easier, as the documents are already in sequence. Decisions and changes to procurement actions can be simply followed by the reader as long as the proper information exists and is filed in historical order.

- **Provide an understanding of the key procurement decisions:** High-quality procurement documentation should highlight all the key decisions made during the procurement process. If particular pieces of documentation are lengthy, adding summary notes will help the future reader glean the critical information of why particular procurement decisions were made. For example, documentation may include a summary note explaining why the second lowest bidder was selected over the lowest bidder due to quality issues.

2. Benefits of Good Recordkeeping

- **Provides one source for all information:** An assembled set of procurement documentation becomes the main source of comprehensive information about a particular procurement. One benefit of establishing the procurement files as the primary source of information is a reduction in duplicate records being kept in other places.
- **Improves ease of access for audits:** Procurement audits are difficult when the documentation is housed in several different files. Auditors give high marks to organizations that are able to produce all the documentation requested. This task is made easier by the creation of procurement files. The World Bank lists recordkeeping as a key evaluation criteria for well-functioning procurement organizations for this reason.
- **Provides information for future procurement of the same commodities:** Many organizations procure the same items over time. It is particularly helpful to draw on the information from previous procurements if records are available and easy to find. The past work can save time required for many procurement steps. Well-prepared documentation can provide information such as the companies that were solicited, price evaluations, and documentation on suppliers that were unsuccessful. The documentation can also provide useful benchmark information, such as pricing and procurement timeline, to measure the progress and success of the current procurement.

- **Saves time by eliminating the need to search for information:** When documentation is not housed in central procurement files, much time can be spent searching for documents when they are needed. Time can be saved in searching through multiple files by creating and establishing the procurement files as the central repository for original documents.

3. Documenting the Procurement Process

Throughout the procurement process, documents are created that should be kept in the procurement files. As previously mentioned, assembling these documents as they are created into easy-to-read, sequentially organized files is a good practice and eases the burden of doing the work at the end. The following section outlines the procurement process and identifies the documents, at a minimum, that should be kept in the procurement files.

a. Program Planning

- **Procurement requisition:** Records should include the original source of data for defining the requirement to procure and official approvals. In many settings, this is an official document such as a procurement request form. The document should define products, quantities, delivery dates, and shipping destination, and should carry the proper approval signatures.
- **Product specifications:** Procurement records should contain the technical definition(s) of the product(s) to be procured. Specifications should include the product information, quality assurance provisions, and packaging and shipping requirements. See Module 2: Specifications for a more detailed description of product specifications.
- **Budget estimate:** Records should include information on the budget established to procure the products. Budget estimates should include the upfront estimate of the total value and the detailed information used to calculate that estimate.

b. Procurement Planning

- **Procurement timeline and summary:** The procurement files should include a document that details the procurement steps, decision points, and sign-off requirements. It should be in a format that captures planned, revised, and actual dates the procurement activities occurred. A summary paragraph or two is helpful to the reader in understanding any changes that were made to the planned procurement process, such as delays or eliminated steps.

- **Bidders list:** A detailed list of suppliers that received the Invitation for Bids or responded to the solicitation should be kept in the procurement files. The list should include the suppliers' names, addresses, primary contacts, telephone numbers, and email addresses, as well as any required government identification or registration numbers.
- **Prequalification document:** If the bidders were required to be prequalified, the files should include supplier applications, evaluations, and the final list of all prequalified bidders.

c. Development of Bidding Documents

- **Record of advertisement:** A copy of the advertisement for open bid should be included in the files, listing the dates it was posted and in what publications. If the advertisement was done on a website or the DG Marketplace (http://www.dgMarket.org, the World Bank and Inter-American Development Bank's Development Gateway Market), then a copy of the posting should be dated and included in the files.
- **Bidding documents:** An original of the complete set of bidding documents sent to bidders must be included in the procurement documentation. Bidding documents are the official offer that was sent to potential suppliers and form the basis for contract documents. The documents should be the final version, with any required approval signatures. Bidding documents are often called into evidence in legal challenges to the procurement, so it is a core piece of procurement documentation that must be kept in the procurement files.
- **Bid security documentation:** The original records of bid securities received and retained should be kept in the procurement files. These documents sometimes come into question in later stages of the procurement process, particularly around payment issues.
- **Record of pre-bid conference:** If a pre-bid conference is held, it is important to document the meeting and results. Key information should be recorded, such as date, time, attendees, record of questions, and responses. This information can be helpful in defending procurement actions in the event of a bidder protest.
- **Modifications to bidding documents:** It is extremely important to clearly document any changes to the bidding documents. A copy of the modification letter and evidence of dispatch to the bidders should be kept in the procurement files.

This information is helpful during bid evaluation to sort out any inconsistencies and ensure that bidders are responding to the same version of the bid request.

d. Selection of Suppliers

- **Proposals from suppliers:** Original proposals received from bidders must be kept in the procurement files. Proposals are also key documents that form the basis for contract documents. Original proposals are often referred to in the subsequent stages of procurement.
- **Record of Bid Opening:** Formal documentation of bid opening proceedings is required in most public-sector procurement systems. Records must be kept of bids opened, meeting minutes, participants, and actions. In many instances, this is recorded in an official memo to the bid evaluation committee (BEC).
- **Record of bid examination:** The BEC must keep detailed records of bid evaluations, adjudications, meeting minutes, and special considerations.
- **BEC summary:** The final recommendations of the BEC are recorded in a summary letter to the required higher authority detailing bid review decisions. These decisions are the final piece, along with the Invitation for Bids and the supplier's bid, that forms the basis for the contract.

e. Contract Award

- **Conditional or unconditional award letter:** Procurement files must contain the award letter to the supplier that accompanies the unsigned contract. This letter outlines key dates and details regarding the execution of the final contract.
- **Performance guarantee documentation:** The letters of credit establishing financial performance guarantee should be kept in the files as evidence that the guarantee was made.
- **Signed contract:** A signed contract is the final result of all the prior procurement process steps. The original contract documents signed by both parties should reside in the procurement files unless there is a regulation that requires a different official storage location. If the original signed documents cannot be stored in the procurement files, a signed copy should be present.
- **Bidder notification:** The procurement files should include a copy of any public notification of contract awards, such as a copy of the newspaper advertisement, including the date it was published. It is also critical to retain any bid dispute and resolution documents; most of these documents will be in the form of letters

between the buyer and seller and possibly the national entity with primary responsibility for procurement oversight.

f. Contract Performance and Monitoring

- **Authorization for shipment:** The contract or letter authorizing the shipment contains details that the purchaser will need to close out the contract and should be retained in the procurement files.
- **Shipping documents:** Many working documents are created during the contract performance stage and should be retained. Bills of lading, packing lists, commercial invoices, and inspection and test reports contain key information regarding the shipment and testing of products.
- **Receiving report:** Other working documents created include proof of receipt, performance scorecard measures, payment authorizations, and Certificates of Analysis. These documents should be kept to provide evidence of acceptance or rejection of the products procured.
- **Miscellaneous correspondence:** Any correspondence that details key contract management elements, especially changes to the contract, should be kept in the procurement files. This correspondence can help the future reader ascertain why certain details of the procurement, such as quantity or price, may have changed from the bidding documents to the contract.

4. Challenges and Solutions

Keeping good procurement records is a difficult task; there are several challenges that must be addressed. There is a great deal of paperwork generated throughout the procurement process, and many of these documents are kept in a variety of working files rather than in a single set of procurement files. The procurement process is lengthy, taking in many cases 12 to 18 months to complete. Complex international competitive bidding can involve multiple procurement personnel. Staff turnover can also compound these challenges. Finally, limitations on storage space for procurement records can cause additional problems for the staff keeping records.

Many of these challenges can be addressed by establishing good recordkeeping disciplines within the procurement unit. Assembling the documentation sequentially through the stages of procurement can assist in reducing the time required to find and assemble the documentation at the end. It is important to establish baseline requirements or a standard operating procedure for which documents are required to be housed in the procurement

files. A useful job aid is a checklist to keep track of the different pieces of documentation that will be assembled to create the complete files. Exhibit J-1 is a sample checklist that can be used to track documents required for the procurement files. Keep at least one copy of key documents in the procurement files if original signed documents are required to be kept elsewhere. The baseline requirements for recordkeeping should establish a financial threshold for documentation. High-value and complex procurements should have the most comprehensive set of documentation, while lower-value procurements may contain only a limited number of key documents. Ensure that when personnel changes are made, new staff have access to documents in process; this will enable them to continue the recordkeeping process. Use a separate room or locking file cabinet to provide secure and limited access to procurement records. Maintain a check-out list for procurement documentation that leaves the storage location; this will allow others to know where the documentation is at any time and who may need to return documents to the central storage location. Apply appropriate record-retention rules for completed documentation. Many countries have a set time period for which documents must be retained for legal purposes. The government national archive agency should be able to provide guidance and assistance in setting up a record retention policy.

Recordkeeping is an important component of the procurement process. It explains what happened, can be used in defense of bid disputes, and can assist with future procurements by providing key information that will save valuable time. Maintaining good records is a process that requires discipline and standardized procedures. In the long run, the upfront efforts of assembling good documentation will reap benefits going forward, making the procurement unit more efficient and effective.

Exhibit J-1

Sample Recordkeeping Checklist

Contract Number:	Bid Number:
Supplier Name:	Bid Title:
Date:	Procurement Contact:

	Included in files	Documentation type	Comments
1	☑	Procurement requisition	
2	☑	Product specifications	
3	☑	Budget estimate	
4	☑	Procurement timeline and summary	
5	☑	List of bidders	
6	☑	Prequalification document	
7	☑	Record of advertisement	
8	☑	Bidding documents	
9	☑	Bid security documentation	
10	☑	Record of pre-bid conference	
11	☑	Modifications to bidding documents	
12	☑	Proposals from suppliers	
13	☑	Record of Bid Opening	
14	☑	Record of Bid Evaluation	
15	☑	Bid evaluation committee summary	
16	☑	Conditional or unconditional award letter	
17	☑	Performance guarantee documentation	
18	☑	Signed contract	
19	☑	Bidder notification	
20	☑	Authorization for shipment	
21	☑	Shipping documents	
22	☑	Receiving report	
23	☑	Miscellaneous correspondence	

Resources

World Bank Procurement Website

The World Bank Procurement website has many helpful tools and guidelines. In many of the World Bank's topical documents on procurement, the subject of procurement documentation is addressed. Effective recordkeeping is also one of the evaluation criteria of World Bank procurement assessments.

http://web.worldbank.org/WBSITE/EXTERNAL/PROJECTS/PROCUREMENT/0,,contentMDK:50002392~menuPK:93977~pagePK:84269~piPK:60001558~theSitePK:84266,00.html

United States Government National Archives

The United States National Archives has an excellent central site for many records management topics. Additionally, the archives include a helpful self-evaluation guide for records management.

http://www.archives.gov/records-mgmt/

http://www.archives.gov/records-mgmt/publications/records-management-self-evaluation-guide.html

K. Regulatory Authorities

This supplement focuses on aspects of regulatory licensing that affect the supply process for reproductive health (RH) commodities; it is neither appropriate nor detailed enough to guide manufacturers seeking regulatory approval or development programs seeking to establish or strengthen national regulatory bodies. For more detailed guidance, see the World Health Organization (WHO) website for its process for manufacturers seeking approval under WHO's prequalification project: http://www.who.int/mediacentre/factsheets/fs278/en/. This process may be similar to requirements of national regulatory authorities.

1. National Regulatory Authorities[†]

National regulatory authorities (NRAs) are government agencies charged with ensuring the safety, efficacy, and quality of particular products available to the population. In some countries, food, drugs, cosmetics, and medical devices are regulated by the same authority. In other countries, national drug regulatory authorities (NDRAs) are in charge of pharmaceutical products—such as antibiotics and hormonal contraceptives—while similar agencies or branches of the government authority regulate medical devices, including condoms and intrauterine devices.[‡] Vaccines and biologics may be addressed by yet another authority, or within a specialized department of the NDRA. For the sake of simplicity, the reader should assume that hormonal contraceptives, pharmaceuticals, and medical devices are regulated together under an NRA.

NRAs in some countries receive their powers through legislation—laws and statutes that define drug policy, assign responsibilities, and provide enforcement. However, in other countries, it is not unusual to find NRAs operating on the basis of policy or tradition rather than legislation. In others, legislation may be in place, but outdated or not enforced.

Administration of the regulatory authority may be centralized or decentralized, depending on the size of the country. The European Union, India, and the United States have strong central regulatory authorities, but many responsibilities are devolved to states or regions.

[†] **Regulatory authorities are called by various names: national regulatory authority, drug regulatory authority, drug administration, national control authority, and national drug regulatory authority.**

[‡] **Intrauterine devices containing copper or a hormonal component may be regulated as pharmaceuticals rather than medical devices.**

a. Functions of the Regulatory Authority

Exact functions of the NRA vary from country to country. In general, however, the NRA:

- Establishes licensing criteria for medicines, pharmaceuticals, vaccines, and medical devices such as condoms, intended for use in the country.
- Establishes procedures for registration of medicines, pharmaceuticals, vaccines, and medical devices such as condoms, to ensure that they are of adequate quality, safety, and efficacy.
- Evaluates the safety, efficacy, and quality of pharmaceutical products and medical devices.
- Issues, modifies, and revokes licenses for pharmaceutical products and medical devices on grounds of quality, safety, and efficacy.
    - May also undertake post-marketing surveillance during the initial 2-year period of marketing a new drug formulation.
- Inspects and licenses all domestic manufacturing premises, importing agencies, wholesalers, distributors, pharmacies, and other retail outlets to ensure that they comply with prevailing regulations and guidelines.
- Controls pharmaceutical product and medical device imports and exports.
- Controls pharmaceutical product and medical device labeling and information dissemination.
    - May also provide public-access websites listing approved products.
- Controls pharmaceutical product and medical device distribution and promotion.
- Investigates adverse events and, if necessary, has the ability to recall products.
- Ensures regular current good manufacturing practice (cGMP) inspections.
- Maintains appropriate laboratory capabilities.

In some countries, the NRAs are also asked to ensure that local industry is protected from outside competition.

b. Product Standards

In order to evaluate, license, and control products, an NRA must first define the standards for each product against which it will be assessed. This is important to procuring entities

because these standards must be reflected in the technical specifications and the terms and conditions.

The composition, active ingredients, and test requirements for most pharmaceutical products can be found in reference manuals called "pharmacopoeias." Each country may publish its own pharmacopoeia, but many do not, choosing instead to rely on one developed by another country. The British, Japanese, and United States Pharmacopoeias; the European Pharmacopoeia; and the International Pharmacopoeia (produced by WHO) are the most widely used.[1] Standards and testing methodologies for a particular drug can vary between these pharmacopoeias, and not all drug formulations are included in each one.

Condom standards and testing protocols are usually not found in pharmacopoeias. However, they are well documented in *The Male Latex Condom: Specification and Guidelines for Condom Procurement* (WHO, 2003).[2]

c. Enforcement of Pharmaceutical Regulations

Pharmaceutical regulations are enforced by controlling the supply mechanism, primarily through licensing at two primary junctures: manufacturing and distribution. In an export/import situation, both countries exert regulatory controls, which may or may not be based on compatible standards. Two situations are described below:

- The NRA of a manufacturing country issues a marketing authorization (product license) and a manufacturing authorization (manufacturer's license) based on its laws, statutes, and regulatory decisions. Compliance is monitored by repeated inspection and testing and documentary review. Failures may temporarily or permanently close an operation.
- The NRA of an importing country issues a marketing authorization (product license or product registration) based on its own laws, statutes, and regulatory requirements. Enforcement is generally handled through the national customs service by denying or allowing products to enter the country. Thus, marketing authorization has a significant impact on the supply of RH commodities.

2. Regulatory Approval

Regulatory approval is an important component of pharmaceutical and contraceptive quality assurance (QA), but it can also work against timely delivery and low prices if the procuring entity does not understand local and international regulatory practices or fails to act on that understanding.

Contraceptives require licensing by at least one national regulatory body before they can be distributed to the population of a country. If they must be imported, they must be approved by the regulatory authority of the exporting country as well as the regulatory authority of the importing country. Typically, requirements on the importing side are enforced by the national customs service. Unlicensed pharmaceuticals are refused entry into the country and quarantined, returned, or destroyed. Regardless of their disposition, they are not available to the RH program for distribution.

The time required for regulatory approval can be significant, but if a procuring entity limits eligibility for bidding to products that have already been licensed by the country's NRA, it also limits competition—sometimes quite severely—and sets itself up for unfairly high prices.

If a procuring entity opens competition to products that have not already been licensed in the country, prices are likely to be lower, but the contract may be delayed while the regulatory licensing process unfolds; this can result in later delivery. The additional time for product registration should be considered in the procurement planning process. Product registration can take from 3 to 12 months, sometimes longer. It depends on the product itself, the capabilities and capacity of the local regulatory authority, and how the authority intends to approach the approval process.

Purchasers that are aware of regulatory processes domestically and internationally are the most likely to be successful at satisfying program needs for safe, effective products; low prices; and specified delivery dates.

a. Product Approval

Before a new medication or medical device is approved for human use, the manufacturer or its sponsor must demonstrate its safety and effectiveness through human studies (clinical trials). These studies can last as long as 8 years and are very expensive. Once a product has proved satisfactory, clinical trial results are usually combined into a large document containing a comprehensive description of the methods and results of human and animal studies; formulation details; manufacturing procedures; shelf life; and specifications for analytical control of starting materials, in-process products, and final products. This collection of information makes up the "regulatory submission" that is provided for review to regulatory authorities in different countries. It is not necessary or practical to repeat these studies each time an application for product approval is submitted in a different country, or with generic formulations of the same product. There are, however, legitimate reasons why additional trials might be designed and undertaken:

- To assess the safety and efficacy of a different dose of a medication than is commonly used (e.g., a 10-mg dose instead of a 5-mg dose).
- To assess the safety and efficacy of an already marketed medication or device on a new kind of patient or for a new indication.
- To assess whether a new medication or device is more effective for a patient's condition than an already used, standard medication or device ("gold standard" or "standard therapy").
- To compare the efficacy of two or more already approved or common interventions for a specific disease within a group of patients who have the disease (e.g., Device A versus Device B; Therapy A versus Therapy B).

b. Country Licenses

Manufacturers wishing to distribute specific pharmaceutical products in a country apply directly to that country's NRA for marketing authorization (a license) and pay stipulated fees. In most cases, manufacturers will not take these steps unless they are reasonably sure of a market in that country or, in the case of public-sector procurement, a large contract. Thus, it is counterproductive for procuring entities to require every potential supplier to license its products with the country's regulatory authority prior to bidding. In order not to limit competition in this way, good public-sector practice suggests that only the winning bidders be required to license their products—but they must do so before the contract becomes effective. Without a valid contract, manufacturers generally will not commit time and resources to production. If the NRA cannot license a product within a short time after a winning bid is identified, the delivery date of the goods may be significantly delayed.

Licensing time frames, procedures, data requirements, and fees vary from country to country and product to product. The NRA's approach to a particular licensing decision determines how long that decision will take. Some general comparisons may be helpful:

1. For established products that have been licensed in other countries, regulatory authorities can "fast track" the approval process; that is, they can rely on the decision of a country with a known stringent regulatory authority. In addition to recognizing it as an expedient option for all regulatory authorities, WHO recommends fast-track approval for agencies that lack the in-house technical expertise to thoroughly evaluate scientific data.

2. Procurement personnel should keep in mind that QA implied by a product license is only as good as the issuing country's NRA. Regulatory authorities recognized as "stringent" are listed in Section 4.a below.
3. Regulatory authorities normally investigate an established product by studying the manufacturer's documentation and undertaking analytical tests on representative product samples. The number and kinds of tests depend on the product, the reputation of the manufacturer, the existence of other QA elements, and the analytical capabilities of the laboratory itself. Pharmaceutical products are typically tested in-house according to nationally recognized pharmacopoeial requirements. Additional QA elements exist for hormonal contraceptives, and WHO recommends a systematic approach to monitoring the quality of oral and injectable contraceptives.[5] Condoms and intrauterine devices are tested in specially equipped and staffed laboratories that are usually not available within a regulatory authority's structure.
4. For products that have recently gone "off patent" and are being offered as generics, regulatory authorities may choose to:
   - License based on "bioequivalence" to other approved formulations (a relatively quick approach).
   - Undertake a new investigation (a longer approach).
5. Regulatory authorities occasionally decide to undertake their own human clinical trials to confirm the safety and effectiveness of a product on their local population. This is a very long approach.

c. Manufacturing License

Along with a product itself (pharmaceutical, contraceptive, medical device, vaccine, etc.), the manufacturing facility in which it is produced must be licensed by the responsible NRA. In most countries, a manufacturing license is based primarily on whether or not the facility is producing medicines in accordance with cGMPs.

cGMPs is a system for ensuring that products produced in a facility are of a consistent quality; it is a system that addresses the process rather than the final product. cGMPs cover all aspects of production, from starting materials to the training and personal hygiene of staff and upkeep of premises and equipment. They involve detailed, written procedures and documented proof that correct procedures are consistently followed at each step in the

manufacturing process every time a product is made. cGMPs also involve records of complaints and adverse reactions as well as records for product recall.

cGMP standards worldwide have been largely harmonized through the elaboration of WHO's cGMPs.[3] Most countries that have formulated their own requirements for cGMPs have based them on the WHO model.

cGMPs are enforced through regular inspections by the government regulatory authority.

d. Current Good Manufacturing Practices Inspections: Domestic Manufacturers

When a domestic manufacturer applies for drug approval, the government regulatory authority inspects the production facility to ensure that all processes and procedures are carried out in compliance with cGMPs. For manufacturers that receive authorization, the regulatory authority continues to perform periodic (including unannounced) inspections to ensure that cGMP compliance is being maintained on a continuous basis. Manufacturers that do not comply with cGMPs do not receive initial or continued authorization to market their products until violations are corrected.

e. Current Good Manufacturing Practices Inspection: Foreign Manufacturers

It is usually not practical for the regulatory authority of an importing country to physically inspect a foreign manufacturing facility. In this case, it may choose to use an international system such as the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce as a substitute for direct inspection.[4] Exporting countries participating in the WHO Certification Scheme provide assurance to importing countries that the exported products:

- Are authorized to be placed on the market in the country of manufacture (or explain why the products are not authorized).
- Are produced in regularly inspected facilities that conform to cGMPs as recommended by WHO.
- Are supported by authorized product information.

Supplementary documentation can be requested through a manufacturer's NRA to include detailed information showing cGMP and QA compliance.

3. International Regulatory Schemes

Since each country (country of origin and country of use) applies its own controls to the manufacture and supply of medicinal products, variations are encountered around the world—sometimes resulting in virtual trade barriers. However, recent regional and international harmonization initiatives have begun to reduce some of this variation in two areas:

- Data requirements for product and manufacturing licenses.
- International acceptance of inspections and inspection reports.

a. The Pharmaceutical Inspection Convention Scheme

The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) is similar in concept to the pharmaceutical QA part of the WHO Certification Scheme in that it is based on mutual recognition of inspection as well as exchange of inspection reports. Unlike the WHO Certification Scheme, admission for participation in the PIC/S system is subject to an evaluation procedure by the inspection authorities of the countries already adhering to the scheme to ensure that any applicant country is operating according to the same standards of cGMPs and inspection.[6]

Both the PIC/S and the WHO Certification Scheme make it possible for NRAs to obtain important information about products manufactured in other countries without having to travel to those countries to inspect manufacturing facilities.

b. The International Conference on Harmonisation

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) brings together the regulatory authorities of Europe, Japan, and the United States, as well as representatives from pharmaceutical industry associations in those regions. The ICH addresses how harmonization of technical guidelines and requirements for product registration might be achieved. Many technical guidelines and requirements have now been agreed upon.[7]

Additional information on the PIC/S and ICH schemes can be found in Section 4.a below.

c. Mutual Recognition Agreements

Mutual recognition agreements serve to recognize that conformity with the regulatory standards of one country is acceptable in another country. Thus, they are "equivalence

agreements" between participating countries. For example, the European Union and the United States have a mutual recognition agreement for medical devices.

4. Reference Materials

a. PIC/S and ICH Countries With Stringent Regulatory Authorities

Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme

The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as the PIC/S) are two international instruments between countries and pharmaceutical inspection authorities. Together, they facilitate active and constructive cooperation in the field of cGMPs. The PIC/S' stated mission is "to lead the international development, implementation, and maintenance of harmonized current good manufacturing practice (cGMP) standards and quality systems of inspectorates in the field of medicinal products."[6] This is to be achieved by developing and promoting harmonized cGMP standards and guidance documents; training competent authorities, especially inspectors; assessing (and reassessing) inspectorates; and facilitating the cooperation and networking for competent authorities and international organizations.

PIC/S Participating Regulatory Authorities (www.picscheme.org)
As of November 2009

Argentina	Australia	Austria	Belgium
Canada	Cyprus	Czech Republic	Denmark
Estonia	Finland	France	Germany
Greece	Hungary	Iceland	Ireland
Italy	Latvia	Liechtenstein	Malaysia
Netherlands	Norway	Poland	Portugal
Romania	Singapore	Slovak Republic	Spain
Sweden	Switzerland	South Africa	United Kingdom

International Conference on Harmonisation

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a unique project that brings together the regulatory authorities and pharmaceutical industry experts of Europe, Japan, and the United States to discuss scientific and technical aspects of product registration. The purpose is to make recommendations on ways to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and

development of new medicines. The objective of such harmonization is to facilitate more economical use of human, animal, and material resources, and to eliminate unnecessary delay in the global development and availability of new medicines while maintaining safeguards on quality, safety, efficacy, and regulatory obligations to protect public health.[7]

ICH Participating Regulatory Authorities (www.ich.org)

As of November 2009

Membership in the ICH is comprised of the regulatory authorities of the European Union, Japan, and the United States. The European Union members include:

Austria	Belgium	Cyprus	Czech Republic
Denmark	Estonia	Finland	France
Germany	Greece	Hungary	Ireland
Italy	Latvia	Lithuania	Luxembourg
Malta	Poland	Slovakia	Slovenia
Spain	Sweden	the Netherlands	United Kingdom

In Europe, the members are the European Union and the European Federation of Pharmaceutical Industries and Associations. In Japan, the members are the Ministry of Health, Labor and Welfare and the Japan Pharmaceutical Manufacturers Association. In the United States, the members are the Food and Drug Administration and the Pharmaceutical Research and Manufacturers of America.

In addition to the regulatory authorities of the participating members mentioned above, the ICH also includes observers from WHO, the European Free Trade Association, and Canada. The observers represent non-ICH countries and regions.

Resources

1. The International Pharmacopoeia

The International Pharmacopoeia comprises a collection of quality specifications for pharmaceutical substances (active ingredients and excipients) and dosage forms together with supporting general methods of analysis, which is intended to serve as source material for reference or adaptation by any WHO member state wishing to establish pharmaceutical requirements.

http://www.who.int/medicines/publications/pharmacopoeia/overview/en/index.html

2. *The Male Latex Condom: Specification and Guidelines for Condom Procurement* (WHO/United Nations Population Fund [UNFPA]/Joint United Nations Programme on HIV/AIDS [UNAIDS], 2003)

This document developed by WHO is designed to provide a set of purchase specifications and procurement guidelines that ensure the highest level of QA for condoms consistent with high-volume purchases, the needs of different populations, harsh environmental conditions, and the probability of less-than-ideal storage conditions. It recommends the prequalification of primary manufacturers and lot-by-lot compliance testing prior to shipping condoms from the country of manufacture. The document also provides a list of manufacturers and testing laboratories *for informational purposes only*. Appearance on this list does not imply endorsement by WHO, UNFPA, or UNAIDS.

http://www.who.int/reproductivehealth/publications/family_planning/9241591277/en/

3. WHO Current Good Manufacturing Practices

cGMPs are that part of QA that ensures products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.

http://www.who.int/medicines/areas/quality_safety/quality_assurance/production/en/index.html

4. WHO Certification Scheme Model Documents

The model certificates on the website conform to the format recommended by WHO. They include a model Certificate of Pharmaceutical Product, a model Statement of Licensing Status of Pharmaceutical Product(s), and a model Batch Certificate of a Pharmaceutical Product.

http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en/

5. *Requirements for the Quality Assurance of Hormonal Contraceptives* (WHO, 1995)

This document summarizes the basic systems required to ensure the quality of imported and domestically manufactured oral and injectable contraceptives. It provides information on national and international regulatory mechanisms that can help to ensure the production and procurement of good-quality products and suggests a systematic approach to monitoring the quality of oral and injectable contraceptives once they leave the manufacturer.

http://www.who.int/reproductivehealth/publications/family_planning/HRP_ITT_95_1/en/index.html

6. Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme

The PIC/S, two international instruments between countries and pharmaceutical inspection authorities, provides an active and constructive cooperation in the field of cGMPs.

http://www.picscheme.org

7. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

The ICH is a unique project that brings together the regulatory authorities of Europe, Japan, and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration.

http://www.ich.org

L. Standard Operating Procedures

Standard operating procedures (SOPs) are written instructions an organization follows to complete a job effectively and efficiently. SOPs document routine and repetitive processes to ensure all employees are consistent in their practices and comply with applicable regulations. Documenting an organization's procedures through SOPs is an effective communication tool that contributes to employees' understanding of their work. Examples of documented procedures are specification development, preparation of bidding documents, and managing the bid process.

1. Importance of Standard Operating Procedures

SOPs are important to an organization for many reasons, some of which include:

- **Ensuring that procurement processes are consistently performed:** There is often more than one person handling procurement processes, each with varying degrees of experience and knowledge. This potentially leads to inconsistency when carrying out procurement processes if a standard is not developed and followed by all members of the organization.
- **Maintaining quality control of the process:** Maintaining quality control within the process helps ensure that an acceptable quality product is procured. By standardizing procurement processes, there is less room for processes to be carried out incorrectly.
- **Ensuring procurements continue uninterrupted and are completed on schedule:** If all personnel understand and utilize SOPs, the process is more efficient. Additionally, SOPs provide personnel with the information needed to complete their work, which, in turn, reduces interruptions in the schedule.
- **Achieving compliance with government regulations:** Adherence to government procurement regulations is a necessity. By incorporating references into the required government regulations, SOPs can increase compliance with the regulations.
- **Serving as a training document for the procurement process:** SOPs can be one of the tools used to aid in the training of new employees. It is also useful to provide refresher SOP training for current employees. SOPs provide a basic set of guidelines required of all employees and serve as important written references for

specific areas of the process. SOPs should always be used as a supplement to training rather than a substitute.

- **Providing a record of the process to aid with future revisions:** It is beneficial to have a written record of the process because it creates a baseline that makes future modifications easy to manage and implement. If there appears to be a continual issue with a certain aspect of the process, then the SOP should be reviewed and revised as needed.

2. Developing and Implementing Standard Operating Procedures

There are seven basic steps involved in developing and implementing SOPs:

Step 1: Define the business goal achieved through the SOPs
There should be a stated purpose for the entire document. This guides the scope of the document for development, and ultimately informs the end user.

Step 2: Select the format
The format should be simple and use graduated steps, graphics, and/or flowcharts. Design the format to present the complexity of the process as simply and clearly as possible.

Step 3: Draft the SOPs
Identify the steps in the procedure in a logical, sequential order. The process steps should be described in clear, simple language, and preferably, the number of steps in the procedure should be limited to ten. See Exhibits L-1, L-2, and L-3 below for guidance on drafting an SOP and an example SOP.

Step 4: Review the draft with employees and management
After completing the first draft, it should be shared with employees and management. Depending on the size of the organization, it may be beneficial to have a select team of employees review and make revisions to the document.

Step 5: Test the SOPs
The best way to test SOPs is to use them. This will identify processes that are missing steps, out of order, or not clear to the user. This type of feedback is imperative prior to releasing the final draft.

Step 6: Approve the final draft
Once the SOPs have been tested and final revisions are recommended, they can be submitted for approval. This approval should be in accordance with the standard practices followed in the organization for the formal release of documents.

Step 7: Implement the SOPs

The most important step, which is often forgotten, is to officially implement the SOPs. Implementation is not simply the notification of the completion of the document and where it can be accessed, but involves training personnel on properly using the SOPs.

a. Standard Operating Procedure Document Format

The general outline for the SOP document should begin with an introduction followed by the content of the document. If the organization has a standard format for official documents, then that should be followed. If not, suggested content for the document is as follows:

- **Introduction:** The introduction should clearly state the purpose of the SOPs, even noting their scope. It is best to define the scope of the procurement processes being addressed within the document; for example, stating that the SOPs cover the procurement process from the time when the procurement requisition is received until the goods are delivered at the central medical stores.
- **Definitions of roles and responsibilities:** There needs to be a brief description of the roles and responsibilities of the procurement officers and any other positions that are referenced within the document. This provides defined lines between units.
- **Reference to procurement policies:** The procurement process is guided by national procurement policies. There should be reference to these policies and any others that would govern the processes within the SOPs.
- **Content—procurement process:** This is the heart of the document, where each process within procurement is carefully outlined and explained. Some examples of procurement process topics are specification development, preparing bidding documents, managing the bidding process, committee protocol, placing a contract, and managing a supplier.

b. Standard Operating Procedure Guidance

- Keep it simple. SOPs with more than ten steps can be overwhelming. The document will likely be used more and followed properly if the number of process steps is kept to a manageable level. If an SOP has more than ten steps, consider breaking it into several logical subprocess SOPs and turning each of those subprocesses into a stand-alone SOP. It is also important to remember to write simple, short sentences, avoiding excessive detail.

- Consider the education, knowledge, experience, and training of the individuals who will be performing the SOP steps. This will be useful in determining the level of detail needed in the document.
- Consider the culture within which people work. For example, if shortcuts are accepted practice, explain the reasons behind certain steps so that SOP users will understand the importance of following *all* the steps in the proper order.
- Address the links between units and process timelines where appropriate. The links between units are important because they show how processes are interdependent.
- Finally, SOPs are a *guide*. They are not intended to replace training of employees.

Resources

Exhibit L-1

General Steps for Writing an SOP

General Steps for Writing a Standard Operating Procedure (SOP)

1. Write a title (with a descriptive verb) that defines the purpose of the SOP.
2. Identify the business unit and/or department for which the SOP has been written.
3. State the purpose of the SOP, including the specific user, in one or two sentences. Include information about process and regulatory standards.
4. List information and materials that are needed to implement the SOP.
5. List, by category, any forms (reference document name and date) required for following the SOP whenever they apply. Use general terms for common forms.
6. Give an overview of the steps in the SOP that describe the process in terms of its major functions.
7. Describe the process.
8. Define terms and concepts. If the SOP contains terms and concepts that readers may be unfamiliar with, define each in its own paragraph so that readers (1) know that there are unusual words or concepts, and (2) can find them easily for use when needed. A long list of terms may fit better in a glossary at the beginning of a document. If you decide that a simple list of terms and definitions is better, include the list within the write-up, perhaps right before the list of steps to be performed.
9. List and explain the process steps in the sequential order in which the SOP user should perform the steps.

Exhibit L-2

Example SOP Document Format

Example Document Format for Standard Operating Procedures

1.1. Purpose

The purpose of the standard operating procedures (SOPs) for the Procurement and Supplies Unit is to provide each member of the unit with clear guidance on conducting transparent, efficient, and consistent procurements on behalf of the Ministry of Health. These SOPs also extend to other units that interact with the procurement unit.

1.2. Scope

The scope of the SOPs addresses the responsibilities of the Procurement and Supplies Unit, beginning with the procurement requisition and ending with the delivery of goods.

1.3. Roles and Responsibilities

The following are the job functions involved in the procurement process. The responsibilities are defined according to the interactions with the procurement unit and its role in the supply process.

Procurement: Procurement is responsible for conducting and managing the purchase of goods, works, consultant services, and services for the Ministry of Health.

User Department: The user department is responsible for initiating the need for procurement.

Accounts: Accounts is responsible for making payments to suppliers on behalf of the Ministry of Health.

Medical and General Stores: Medical and General Stores is responsible for the receipt, storage, and delivery of any goods imported into Dharma *[fictitious name]* for the Ministry of Health.

Clearance Agent: The clearance agent is responsible for customs clearance for any goods imported into Dharma for the Ministry of Health.

1.4. References

The following are supplemental documents that provide guidance and regulations for procurement at the Ministry of Health.

1.4.1. Dharma Public Procurement Authority
1.4.2. Procurement Procedures Manual
1.4.3. Procurement Plan
1.4.4. World Bank Guidelines

Exhibit L-3

Example SOP

Dharma *[fictitious name]* Ministry of Health
Procurement and Supplies Unit
Standard Operating Procedures

Procedure: Bidding Documents
Unit: Procurement and Supplies Unit

Subject: Preparation of bidding documents for Goods	**Procedure #:** 2.3.2

The following steps are required to prepare bidding documents for Goods for an open bid.

1. Prior to preparing the bidding documents, establish the following information:
   a. Review and verification of technical specifications.
   b. Schedule of Requirements.
   c. Delivery schedule.

2. Obtain the template for the standard bidding documents for Goods. The following sections of the templates of the standard bidding documents need to be completed:
   a. Invitation for Bids.
   b. Bid Data Sheet.
   c. Special Conditions of Contract.
   d. Supply requirements:
      i. Schedule of Requirements.
      ii. Specifications.
   e. Sample forms.

3. Draft a letter/memorandum addressed to the Dharma Public Procurement Authority (DPPA) requesting the review and approval of the bidding documents. The letter to the DPPA must be signed by the Permanent Secretary.

4. To obtain approval of the bidding documents, send the letter/memorandum to the DPPA with a hard and a soft copy of the bidding documents.

5. A hard copy of the bidding documents should be retained for the files of the preparer.

Reference: Procurement Procedures Manual—
Section 20: Introduction to the Bidding Documents
Section 21: Bidding Documents
Section 22: Conditions of Contract
Section 23: Schedule of Requirements
Section 24: Technical Specifications
Section 25: Bidding Document Forms
Section 26: Approval & Distribution of the Bidding Documents

Websites

***Dairy Farm Business Standard Operating Procedures: A Writing Guide* (The Pennsylvania State University College of Agricultural Sciences, Agricultural Research, and Cooperative Extension, 2001)**

This document outlines the steps for writing SOPs. While the concept is based on the dairy farm business, the principles can apply to any process.

http://dairyalliance.psu.edu/pdf/ud011.pdf

***Guidance for Preparing Standard Operating Procedures* (United States Environmental Protection Agency [EPA], 2007)**

This document is a standard working tool that can be used to document routine quality system management and technical activities. While the document is written for the EPA, the principles apply to any process.

http://www.epa.gov/QUALITY/qs-docs/g6-final.pdf

M. World Bank Standard Bid Evaluation Form

The World Bank Standard Bid Evaluation Form (SBEF) is provided in its entirety as a reference document for purchasers to consider using as a model when evaluating bids procured through international competitive bidding, limited international bidding, and with appropriate modifications, national competitive bidding.

The SBEF format developed by the World Bank is comprehensive; supports a clear, transparent process; and generates the documentation necessary to support the award recommendation. It emphasizes compliance with technical, quality, delivery date, and other contractual requirements *first*, before considering price. This approach aligns with the overarching tenets of good reproductive health procurement practices.

See Module 7: Selecting Suppliers for more information. (Please note: The SBEF was developed for use by projects funded under World Bank loans and credits; thus, some details and references are not applicable for other procurement situations. The SBEF was used by the World Bank for all projects initiated up to October 2006. As of the date of publication of this *Toolkit*, the World Bank had not released an updated SBEF. Therefore, the original SBEF is used in Module 7 as an illustrative model that could be adapted for use by a wide range of procuring entities.)

The World Bank SBEF is available on the World Bank website at http://go.worldbank.org/K51NBXRVV0.