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Session 6: Enhancing Pharmaceutical Procurement

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Session Objectives

- Recognize the characteristics of a good pharmaceutical procurement system
- Identify and describe the steps in the procurement cycle
- Discuss regional collaboration for procurement
- Discuss procurement of pharmaceuticals using USAID funds
- Discuss the challenges in the procurement of HIV/AIDS, TB, and malaria supplies

Session Outline

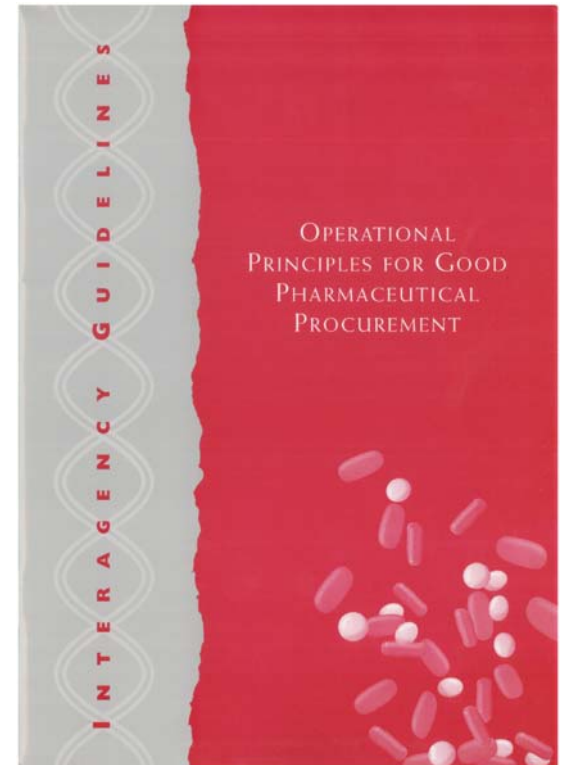
- Introduction
- Operational principles for good procurement
- The procurement cycle and methods
- Regional collaboration for procurement
- USAID procurement
- Procurement guidelines
- Challenges in procurement
- Case study

Objectives of a Good Procurement Program

- Procure the right drugs in the right quantities at the lowest possible total cost
- Select reliable suppliers of quality products
- Ensure timely delivery and notification

Operational Principles for Good Procurement

- Efficient and transparent management
- Drug selection and quantification
- Financing and competition
- Supplier selection and quality assurance



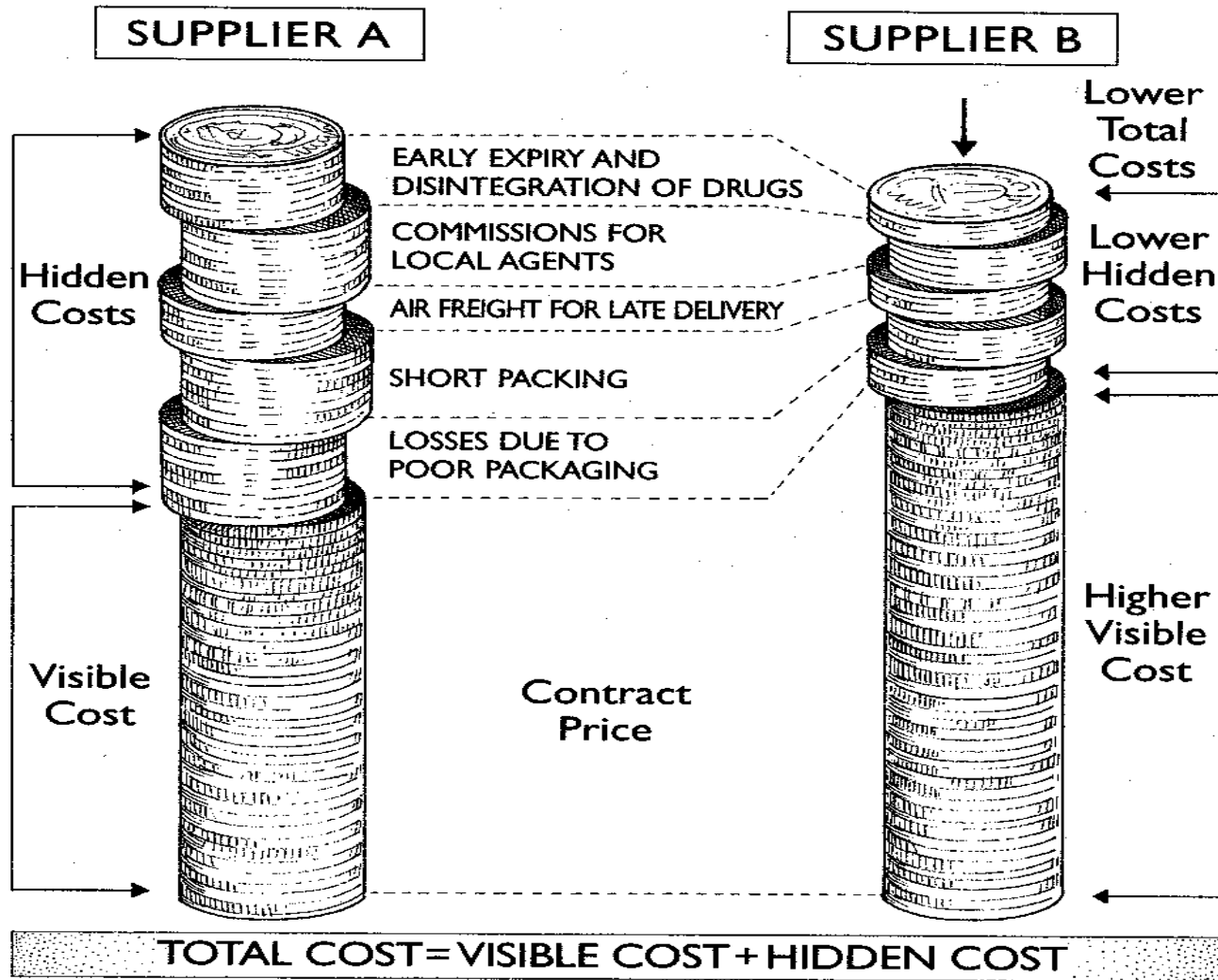
Good Procurement Practices (1)

- Generic name
- Limited to essential medicines list or formulary list
- Bulk purchases
- Formal supplier qualification and monitoring
- Competitive bidding process
- Commitment to a sole source

Good Procurement Practices (2)

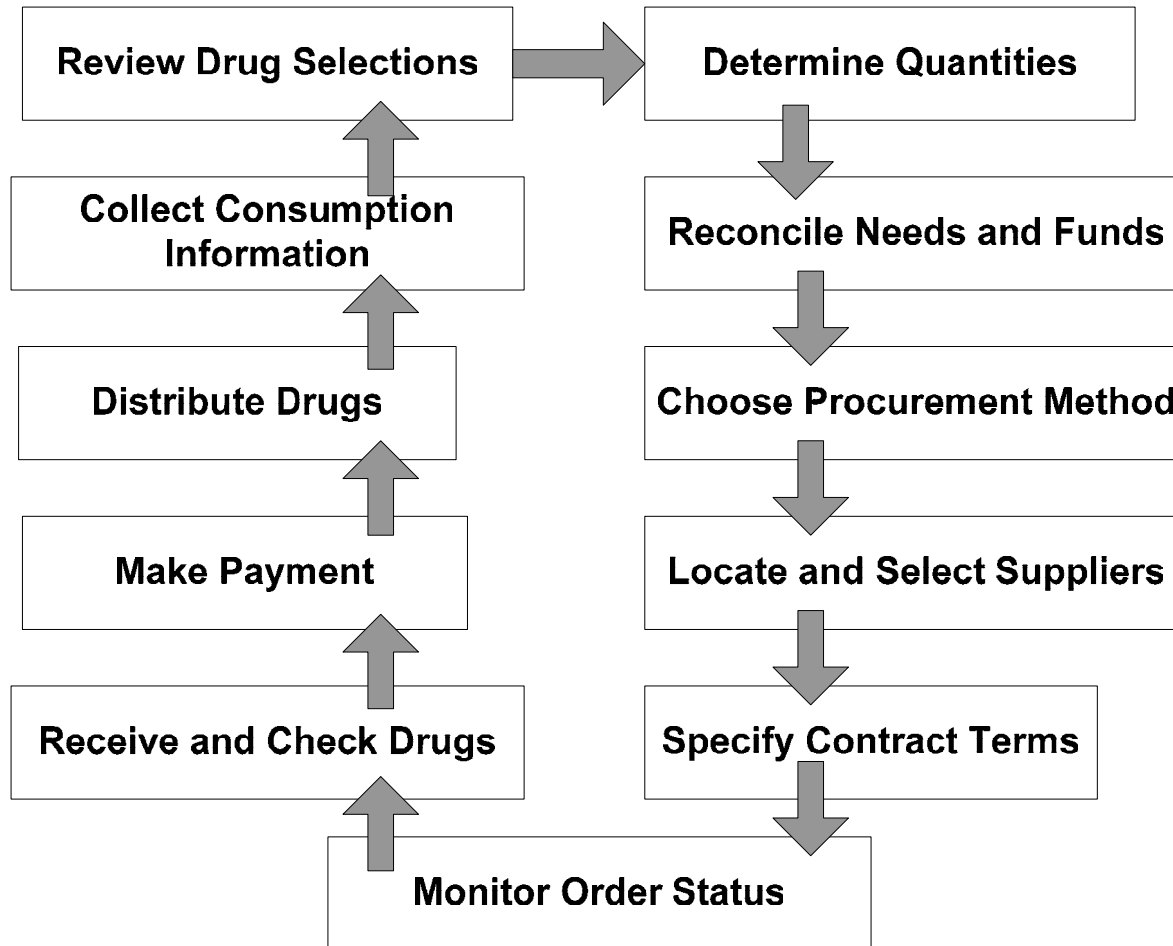
- Order quantities based on reliable estimate of actual need
- Reliable payment and good financial management
- Transparency and written procedures
- Separation of key functions
- Product quality assurance program
- Annual audit with published results
- Regular reporting on performance

Impact of Hidden Costs in Procurement



Source: MSH: Management Sciences for Health. Used with permission.

The Procurement Cycle



Source: MSH: Management Sciences for Health. Used with permission.

Procurement Methods

Method	Effect on Price	Lead Time	Work Load
Open Tender	Usually lowest prices	Moderate to long	High
Restricted Tender	Favorable	Moderate to long	High
Competitive Negotiation	Can be favorable	Short to moderate	Moderate
Direct Procurement	Usually highest prices	Short to moderate	Low

Defining Regional Collaboration for Procurement

- Wide variation exists in types of regional collaboration for procurement
- Spectrum of options ranges from the simple sharing of information to the actual pooling of resources and requirements combined with contracting and purchasing by an agency acting on behalf of the group of countries

Models of Regional/Country Collaboration

- Information Exchange
 - Informed buying
 - Coordinated informed buying
- Pooled Procurement
 - Group contracting
 - Central contracting

Characteristics of Models

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

Pooled Procurement Initiatives

Name of Initiative	Year	No. of Countries	Status
FORMED	1986	3	Defunct
OECS/PPS	1986	9	Ongoing
Gulf Cooperation Council	1986	6	Ongoing
Arab Maghreb Union	1989	3	Inactive
ACAME	1996	6	?
Pacific Islands	1999	3	?

Advantages of Pooled Procurement

- Reducing drug costs through economies of scale
- Harmonizing drug registration among countries
- Harmonizing standard treatment guidelines (STGs) and essential medicines lists (EMLs)
- Improving quality assurance systems
- Improving supplier performance

Lessons Learned from Pooled Procurement

- Political will and organizational commitment
- Permanent and autonomous secretariat
- Harmonization and standardization
- Strong procurement systems
- Finances/reliable payment
- Quality assurance

USAID Procurement Requirements

- Pharmaceutical products
- Safety, efficacy, and quality
- “Buy America”
- Protection of U.S. patents

Challenges in Meeting USAID Procurement Requirements (1)

- Lack of guidance material to assist in what is perceived to be a complex process
- Preferential procurement of U.S. S/O, FDA-approved products may result in:
 - Increased costs and delays
 - Reduction in the impact of the program
 - Negative effect on the harmonization of pharmaceutical products within a country
 - The approved product may not be the most appropriate product for that program in the country context

Challenges in Meeting USAID Procurement Requirements (2)

Missing information

- Justification for not procuring a U.S. source of origin pharmaceutical product
- Information on the capacity of the program to use the product appropriately
- Data to attest to the safety, efficacy, and quality of the product

Options for Meeting Challenges

- Briefing document to provide guidance to cooperating agencies (CAs) and Missions on USAID procurement guidelines and procedures
- Technical assistance to USAID Missions and CAs in preparing requests for approval
- Implementation of Supply Chain Management System (SCMS)

World Bank Procurement Guidelines

- Principles
 - Need for economy and efficiency
 - Need to give all eligible bidders opportunity to compete
 - Encourage development of local industries in borrowing country
 - Importance of transparency

World Bank Procurement Methods

- International competitive bidding
- National competitive bidding
- Limited international bidding
- International or local shopping
- Direct procurement (sole sourcing)
- Cost-based selection
- Quality-based selection
- Limited budget selection

ARV Registration and Procurement – The Case of Ethiopia (1)

Background

- ART supported by GFATM and the U.S. President's Emergency Plan for AIDS Relief
- Distinct sites will receive ARV drug support from the Emergency Plan or GFATM
- First-line ARVs for adults have been introduced only for paying patients
- National treatment guidelines were under revision at the time of quantification and procurement
- Drug requirements for 6 months are to be received in two shipments

ARV Registration and Procurement – The Case of Ethiopia (2)

Registration

- Manufacturers are not interested in registering some drugs in Ethiopia
- Some manufacturing sites and pack sizes vary from those of registered products
- Full provision of second-line drugs has to be postponed until national treatment guidelines are endorsed

Quantification

- Uptake of newly introduced pediatric and second-line treatment unknown
- Intensive collaboration crucial for agreement on drug selection and projection of the capacity for scaling up

Pharmaceutical Donations

- Types
 - Solicited
 - Unsolicited
- Problems

Issues in Procurement of ATM Drugs and Supplies (1)

- Quantification of needs
- Chaotic and confused global market situation
- Doha Declaration on the TRIPS Agreement
- Donation programs
- Limited number of sources/suppliers
- High cost of supplies

Issues in Procurement of ATM Drugs and Supplies (2)

- Potential for corruption
- Varied and changing treatment regimens
- Variety of formulations
- Quality concerns
- Limited knowledge
- Limited sources of raw materials

Common Procurement Challenges

- Absence of a comprehensive procurement policy
- Inadequate rules, regulations, and structures
- Public sector staff with little experience and training to respond to market situations
- Government funding that is insufficient and/or released at irregular intervals
- Donor agencies with conflicting procurement regulations
- Fragmented drug procurement at provincial or district level
- Lack of unbiased market information
- Corruption and lack of transparency

Summary

- Characteristics of a good pharmaceutical procurement system
- Steps in the procurement cycle
- Regional collaboration for procurement
- USAID procurement procedures
- Challenges in the procurement of HIV/AIDS, TB, and malaria supplies