Summary Guide for Policymakers, Ministry Personnel, and Program Managers

Contents

A. Introduction

B. Where Policymakers Have an Impact on Reproductive Health Supply

C. What Policymakers Need to Know About Reproductive Health Supply/Goods

D. The Reproductive Health Supply Process

E. Issues That Create Significant Delays and Other Problems in the Supply Process

F. Summary of Challenges

G. Glossary and Acronyms

A. Introduction

Successful procurement and management of contraceptives, pharmaceuticals, and other commodities is crucial to the success of reproductive health (RH) programs because they require uninterrupted supplies of safe, effective products. "Uninterrupted" is a key word for these products, as they must be used on a regular basis in order to be effective and provide the required protection. Programs that cannot support regular use of contraceptives do not achieve their objectives, acquire a poor reputation, and soon lose their clients.

Developing and transitional countries have a great need for dependable RH services in the public sector, but in these same countries, public-sector procurement can be a challenging job, often encumbered by problems and delays that generate stock-outs.

The skill and speed with which the supply process is handled is limited by the environment in which it operates. This environment includes laws and regulations, resources and infrastructure, routine practices of the government apparatus, and decisions made by those in authority.

Policymakers at every level have an impact on this all-important environment… either positively or negatively.

This Summary is Written for:

1. Policymakers who are part of larger government bodies and heads of ministries or administrative units serving as legislative delegates, as well as higher-level government officials. This group may have little or no specific exposure to RH issues in general and procurement of contraceptives and pharmaceuticals in particular. They may never have considered how the quality and timeliness of these products affect the "greater good" of the people they are pledged to serve.
2. Health ministry personnel who sometimes become involved in parts of the RH supply process—generally the budgeting and financial aspects—but may not be aware of RH supply goals, good public-sector procurement practices, or operational details within their own systems that can affect the quality and timeliness of RH supplies.
3. Program managers without responsibility or requirements in the area of RH supply but who may have parallel needs—for example, managers of HIV/AIDS programs that purchase condoms or treatment drugs.

4. Others who may find this summary useful as a supplement to the detailed learning modules.

For convenience, the remainder of this Summary Guide will include all four audiences under the general heading of "policymaker."

The objective of this Summary Guide is to help readers develop the insight necessary to effectively support the primary goals of RH supply: **safety, efficacy, and timely delivery of the product**. To help achieve this objective, the Guide addresses the following key topics:

- Identifying where policymakers have an impact on RH supply.
- Identifying what policymakers need to know about RH supply.
- Providing an overview of the RH supply process.
- Identifying issues that lead to delays and other problems in the RH supply process.

A general understanding of pertinent processes and key issues will hopefully lead to beneficial decisions, or at least to decisions that will cause no harm. The Guide also seeks to instill realistic expectations about RH supply matters.

B. Where Policymakers Have an Impact on Reproductive Health Supply

The following are some of the key areas in which policymakers can have an impact—either favorably or unfavorably depending on the decisions made—on the overall effectiveness and efficiency of the RH supply process:

- Drafting and enforcing public procurement laws and regulations, including anticorruption measures.
- Interpretation of policies on fair competition. For example, World Health Organization (WHO) prequalification as a quality assurance (QA) measure is sometimes challenged inappropriately as limiting competition.
- Staffing policy can negatively impact personnel in procurement positions (e.g., routine rotations sometimes lead to untrained, inexperienced procurement personnel or personnel lacking specific knowledge required for RH product procurement).
- Budget allocations:
    - Financing and support for staffing and internal infrastructure.
    - Financing for product procurement.
- Management of funds (allocated funds are sometimes unavailable when the obligation to the supplier must be paid).
- Efficient, timely decision-making and approval processes.
- Building reputations for trouble-free international commerce and fair competition, which attracts good suppliers and increases competition.
- Taxation policy. (Must a program pay taxes on goods that will be used in the public sector?)
- Regulatory and product licensing issues and procedures.
- Import procedures and restrictions.
- Disposal of expired or defective goods.
- Inspection and acceptance policy.
- Centralized versus decentralized procurement.

While generally left to the responsible program manager, other policymakers may play a part in decisions about:

- Finalizing quantification data.
- Determining the method mix for contraceptives.
- Allocating budgets and other resources.
- Adding new products to the essential medicines list.
- Selecting the procurement option (e.g., procurement handled directly by staff or indirectly through an external organization).
- Assigning procurement responsibility.

C. What Policymakers Need to Know About Reproductive Health Supply/Goods

1. What Are "Reproductive Health Goods" and Where Do They Come From?

WHO publishes *The Interagency List of Essential Medicines for Reproductive Health*, which presents the current international consensus on the rational selection of essential RH goods and medicines.[1] This list includes a wide range of pharmaceutical goods and medicines, from anesthetics and anti-infective medicines, to disinfectants, contraceptives, and immunologicals that have been selected to provide comprehensive reproductive health medical care.

For the *Procurement Capacity Toolkit* and this Summary Guide, this list of RH goods and medicines has been narrowed to focus primarily on contraceptives, which include hormonal contraceptives in pill or injectable form, intrauterine devices, implants, and condoms.

The technology required to produce contraceptives ranges from highly sophisticated steroid synthesis and compounding to factory floor injection molding and latex dipping—all very different manufacturing environments requiring specialized, expensive equipment and quality control measures that often rule out local production in developing economies. Some of the pharmaceuticals are more likely to be produced locally in developing countries.

a. What This Means for the Reproductive Health Supply System

Most contraceptive purchases involve doing business with international manufacturers. This requires managing the transfer of funds through the international banking system and observing international trade conventions. It also brings into play widely recognized standards for public procurement; these are reflected in the expectations of potential suppliers. Import procedures and customs clearing systems enter the picture, as do licensing and regulatory issues. The supply process will be interrupted if any of these functions are performed poorly.

[1] **World Health Organization (WHO) et al. *The Interagency List of Essential Medicines for Reproductive Health.* Geneva: WHO; 2006. Available at: http://www.who.int/medicines/publications/essentialmedicines/WHO-PSM-PAR-2006%20I_Rev.pdf.**

2. Overarching Requirements: Quality and Timeliness

a. Quality

In purchasing products for the RH program, safety and efficacy take precedence over cost. In this special area of health, a poor-quality product has the capacity to do irreparable harm, and at the very least, waste public money by doing nothing at all. Unfortunately, unscrupulous sellers are found in many countries, selling fake, outdated, and substandard products to unsuspecting buyers at very low prices. In any situation, "bargain" prices can be an indicator of poor-quality products.

For this reason, in all budgeting exercises for RH goods, it is necessary to incorporate measures to ensure the quality and efficacy of the product.

b. Timeliness

As explained earlier, RH programs must be able to support regular use of contraceptives by their clients. The procurement process incorporates measures to promote timely, dependable resupply, but the outcome is always vulnerable to problems in the wider environment.

3. Quantity Implications

A single unit or even a month's worth of a contraceptive product is a minimal investment, but the annual quantity requirements for a target population add up to relatively high values.

a. What This Means for Reproductive Health Supply

1. Potential suppliers can become forceful when high values are at stake. They may attempt bribery or other corrupt practices, which, if successful, may drive away potential bidders in the next round of RH procurement. Or, unsuccessful competitors may try to subvert award decisions that are not in their favor—leading to long delays.
2. Rules for government and organizational spending are most stringent at high financial "thresholds," meaning the procurement process for contraceptives is likely to be lengthy and complex.

4. Regulation of Reproductive Health Goods by National Regulatory Authorities

Regulatory licensing by national regulatory authorities (NRAs) is primarily a means of protecting populations from unsafe, ineffective drugs and medical devices.

Worldwide, manufacturers of drugs and contraceptives must apply to local regulatory authorities for permission to market or otherwise distribute their products in a country by submitting pertinent safety and efficacy data and samples. The local NRA reviews these data, does testing, and grants or refuses licensing in a process that is often time consuming and expensive for the manufacturer. Thus, licensing a product is usually not undertaken unless the manufacturer is relatively sure of obtaining a market share in the target country.

Enforcement of regulatory licensing is handled in part by national customs services; unlicensed products are denied entry into a country, turned back, or quarantined and eventually destroyed.

a. What This Means for Reproductive Health Supply

Since most developing countries need to import contraceptives, local regulatory licensing is critical. Good public-sector policy on competition requires the purchasing authority to accept bids from all potential suppliers, not just those offering already licensed products. Should the bidder of an unregistered product win the competition, the manufacturer of the offered product must obtain licensing (marketing authorization) from the local regulatory authority before a contract can become effective. The problem that arises has to do with the length of time it takes for such licensing and whether or not it will delay delivery enough to impact the supply situation. Some governments have dealt with this problem at the policy level by approving a "fast-track" regulatory procedure that accepts evidence of licensing in countries with known stringent regulatory authorities in lieu of prolonged and detailed investigations into the product's safety and efficacy by the local authority.[2]

For more information, see Supplementary Topics, Section K: Regulatory Authorities.

5. Principles of Good Public-Sector Procurement

Good public-sector procurement is based on competitive bidding and a fair, well-documented supplier selection process. Development banks and donors around the world,

[2] For example, countries that are members of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) have known stringent regulatory authorities. For more information on the PIC/S and ICH, see Supplementary Topics, Section K: Regulatory Authorities.

as well as many governments, require these widely held standards and procedures of entities using their funds. In the past, details have varied by institution, but in recent years, the Organisation for Economic Co-operation and Development has spearheaded a movement to harmonize rules, procedures, and documents across their membership. Health-sector procurement involves additional product challenges. Products such as contraceptives, pharmaceuticals, and vaccines have unique QA and regulatory requirements that are added to the normal provisions for public-sector procurement.

6. Who Works on Reproductive Health Supply?

In a traditional setting, program personnel (usually with public health backgrounds) are responsible for program planning tasks, and a separate procurement unit is responsible for procurement process tasks. In addition, critical contributors, such as the Ministry of Finance, pharmacy specialists, the RH unit, accounting, customs clearing, and central stores, play peripheral but important roles.

It is not uncommon to see program management doing some of the procurement processing tasks and vice versa; the work can be divided in any way that suits the situation, as long as the assigned personnel have appropriate skills and product knowledge.

7. How Long Should it Take to Purchase Reproductive Health Goods?

Faster is not always better when it comes to quality and cost. Twelve months or more may elapse from the time funding is assured until goods are ultimately delivered—even under a well-run international competition. The skill and diligence of the procuring entity are important factors in minimizing the time it takes to purchase RH goods, but they are not the entire story. Bottlenecks often occur in areas over which the procuring entity has no control. For example, approvals may be held up due to the absence or distraction of a key individual. See Module 5 for additional information on the importance of proper procurement planning.

8. Financing the Annual Reproductive Health Goods Requirement

Funds for procurement of RH goods may come from a government's own revenue budget, loans or grants from development banks (e.g., the World Bank), a bilateral donor arrangement, foundation gifts, etc. **Confirmed funding**—regardless of the source—**is the most critical link in the RH supply process**. In addition, the source of funding may

dictate how the procurement should proceed, who should do it, and what markets can be solicited for offers. For example, a development grant may stipulate procurement through a United Nations supply agency (e.g., the United Nations Population Fund [UNFPA] or the United Nations Children's Fund [UNICEF]) for certain products. A government health program using its own revenue funds, on the other hand, may require its centralized national procuring entity to carry out a competitive bidding process for its requirements.

D. The Reproductive Health Supply Process

There are three phases of the RH supply process: program planning, procurement process, and contract performance. Each phase is composed of different elements. The table below is a visual representation of the process.

Three Phases	Ten Elements
I. Program Planning	Defining Reproductive Health Supply Requirements
	Specifications
	Assessment of Procurement Options
	Budget, Funding, and Procurement Requisition
Critical Link: Funded Procurement Requisition	
II. Procurement Process	Procurement Planning
	Developing Bidding Documents and Inviting Offers
	Selecting Suppliers
	Contracts
Critical Link: Signed Contract and Payment Guarantee	
III. Performance	Contract Performance and Monitoring
	Delivery of Goods
Critical Conclusion: Delivery and Acceptance of High-Quality Products	

Critical components link each stage in the supply process:

- Funding.
- Signed contract.
- Payment guarantee.
- Delivery of high-quality products.

Failure at any critical link will terminate the supply process.

Additional details regarding the elements within each phase of the supply process and the critical components linking each phase can be found in the individual modules of the *Toolkit*.

Phase I: Program Planning

The first time a new policymaker becomes aware of the RH supply program is often during preparation and discussion of the annual budget. Budget requests for RH commodities are usually the result of a long, iterative process of planning and decision-making. The first part

of the process is requirements definition, followed by cost estimation, and, finally, the establishment of a budget requirement.

The modules addressing the elements of the program planning phase are as follows.

Module 1. Defining Reproductive Health Supply Requirements

This is the process of selecting the appropriate products and forecasting the quantities to be purchased. These processes are based on program coverage goals, method mix, existing inventories, required delivery dates, and other program factors.

Module 2. Specifications

Technical specifications are one of the most important elements of procurement:

- They provide detailed information to suppliers about the goods to be purchased.
- They are the benchmarks against which the purchaser will judge the technical responsiveness of suppliers' bids.
- They form the basis for the contractual obligation of the supplier to the purchaser.
- They are the criteria against which the purchaser will determine the acceptability of specific goods prepared by the supplier for shipment.

Specifications can be used to define a variety of areas, such as product information (quantity, size, color, and registration), manufacturing requirements (standards for raw materials and current good manufacturing practices certification), testing requirements, and packaging and shipping requirements—all details that when taken as a whole ensure product quality and acceptability to the end user.

In addition to specifications that are clear, accurate, and complete, public-sector procurement requires that specifications be prepared in a way that will encourage maximum competition. They must be "product neutral." In other words, they must use generic terms, relative characteristics, and performance requirements rather than brand names and superficial descriptions. If there is no way to avoid stating a brand name, it must be followed by "or equivalent." Nonfunctional requirements (such as color and exact dimensions) must have strong justification and may not be used simply to eliminate all but a specific brand.

A challenge and requirement at this phase is to manage the process to ensure specifications are complete, comprehensive, and accurate, including obtaining input from all relevant governmental bodies, technical specialists, and program staff.

Module 3. Assessment of Procurement Options

Most organizations choose one of the following approaches when assessing their procurement options:

- Contract directly with a manufacturer (or its agent).
- Purchase goods from a distributor that has contracted with manufacturers for large quantities which it resells.
- Hire a procurement agent to purchase goods on their behalf.

The choice directly affects cost, so it must be considered when developing a budget. Contracting directly with a manufacturer or its agent usually returns the lowest unit price, but requires the most expertise. The decision is made based on what is possible, what is practical, who can/will do the procurement work, and cost implications. In many cases, a program will use different options for different products. Program managers normally decide on the best course of action for their circumstances; however, organizational and government policies play a role.

The three main options and their variations are shown below. Some of the requirements for each, plus financial commitments and risk factors, are summarized in Exhibit S-1. Additional discussion can be found in Module 3 and Supplementary Topics, Section F: Procurement Agents, and Section G: Procurement Models.

Exhibit S-1

Procurement Options Table

Requirements and Results for the Reproductive Health Purchaser							
Procurement Option	**Purchase Quantity**	**Foreign Exchange Required**	**Procurement Skills Required[1]**	**Infrastructure[2]**	**Product Cost**	**Fee[3]**	**Risk Level[4]**
Direct - international bid	Large	Yes	High	High	Low	No	Low
Direct - international bid with private agent	Large	Yes	Med	Med	Med	Yes	Med
Indirect - public procurement agency	Large	Yes	Low	Low	Med	Yes	Low
Indirect - private procurement agent	Med to large	Yes	Med	Med	High	Yes	Med
Indirect - parastatal procurement service	Any	No	Low	Low	High	Yes	High
Indirect - regional buying alliance	Any	Yes	Low	Med	Med	Yes	Med

1. Required level of procurement skills needed to administer the procurement option.
2. Ministry of Health infrastructure required to support procurement.
3. Fee included in the cost.
4. Risk of a poor-quality product. Risk level is based on product knowledge, skill of agent, and proper administration.

a. Direct Procurement

- International competition.
- International competition using a private procurement agent.
- Sole-source procurement.
- Small-scale national competition.

b. Indirect Procurement

- International supply service.
  - Public-sector agency (e.g., UNFPA, UNICEF).
  - Private-sector agency (e.g., IDA Foundation, Missionpharma).
- International procurement agency (the private-sector Crown Agents).
- Parastatal procurement service.
- Regional buying alliance (where one exists).

Module 4. Budget, Funding, and Procurement Requisition

a. Cost Estimates

Cost estimates are not as straightforward as they might seem. Prices for each product vary widely based on how the procurement is done (see the procurement options above) and the level of the supplier in the distribution chain. Moving down the distribution chain (from manufacturer to retail seller) adds costs and a profit margin at each level that is passed on to the purchaser. In addition, discounted public-sector prices are available for some products from some international suppliers and manufacturers. Access to these special prices is usually tied to a country's gross national income (GNI), with the poorest countries paying the lowest prices. Large-quantity purchases often rate discounted pricing as well. Thus, the lowest prices may be seen when a low-GNI country is purchasing large quantities from a high level of the distribution chain. The GAVI Alliance provides support to national governments to procure discounted vaccines through the GAVI Fund. Eligibility is determined by national income, and only countries with a GNI per capita of less than US$1,000 in 2003 qualify. Currently, there are 72 eligible countries.[3]

b. Assessment of Supply Possibilities

In order to develop useful cost estimates, the procuring entity must determine the types of sellers available to it for each product. Supply possibilities are dependent on issues such as:

- Access to convertible currency and banking for international purchases.
- Agreements with financing organizations.
- National trade barriers.

[3] For more information, see http://www.gavialliance.org/support/who/index.php.

- Regulatory constraints.
- What level of supplier is likely to be interested based on quantity requirements and expenditure levels.

c. Pricing Research

The procuring entity must also research current product pricing information and associated costs. The following resources can be used for this purpose:

- Quantities and last prices paid.
- Direct inquiries to manufacturers.
- Published price guides.
- United Nations agency pricing.
- Discounted pricing, if eligible (low GNI).
- Associated costs, including:
    - Taxes and fees.
    - Freight and insurance costs and modality of last shipments.
    - Inspection and testing.
    - Inland transport.

d. Calculating the Budget Requirement

The estimated cost to fulfill the coverage target is calculated by multiplying each item by its likely price and adding associated costs. If the estimated cost is more than the amount likely to be available—as is often the case in developing countries—the RH program must make adjustments to the number of clients it can serve, delay some of the procurement and draw down on buffer stock (if any exists), or find additional funding. See Module 4 for additional information on budgeting.

e. Procurement Requisition

Once funding has been assured, the program requiring RH products can issue a procurement requisition to the entity responsible for procuring the goods, providing detailed information about product requirements by item, quantity, delivery date, and technical specifications.

Phase II: Procurement Process

Between funding a procurement request and a signed contract lies a large body of decision-making and prescribed activity generally referred to as the "procurement process."

Module 5. Procurement Planning

The procuring entity selects an appropriate method for purchasing the required goods if it has not been specified by the financing organization in policies tied to financial thresholds. For contraceptives, the procurement method is usually international competitive bidding either open to all or restricted to products and manufacturers that have been prequalified in some manner.

Procurement planning also establishes expectations for a delivery date, a time frame for payment, and a framework for monitoring progress.

Module 6. Developing Bidding Documents and Inviting Offers

Bidding documents contain rules and conditions for bidding, state how a winning bidder will be chosen, and prescribe conditions of the resulting contract (including the method of payment). They also include formal specifications, quantity requirements, and a delivery schedule. Under good public-sector procurement practice, everything must be clearly stated; nothing can be changed once the bids are opened, so the process of developing bidding documents necessarily requires many careful decisions. At times, the procuring entity will need information or a decision from the policymaker level before it can proceed. Delays in obtaining information and decisions can easily translate into a delayed procurement process and critical shortages in the supply chain. In addition, failure to incorporate product quality protection into bidding documents and subsequent contracts can result in receipt of substandard products.

Most governments and organizations use model (standard) bidding documents that contain mandatory wording in line with official policy. Clauses specific to the procurement are filled in by the procuring entity. Finished documents are often more than 50 pages long once all the necessary schedules and bidding forms have been included, and they are sometimes difficult for casual readers to understand.

After the bidding documents have been prepared and approved, the procuring entity alerts potential suppliers about the opportunity to bid. This is done through advertisements in

local and national publications as well as on public-access websites and bulletin boards. Sometimes trade organizations are also notified.

Bidding documents are numbered and sold upon request to potential bidders at a nominal cost—enough to ensure that the party is actually interested in bidding, but not so much as to restrict competition. The purchasing office records contact information for everyone who receives bidding documents so they can be notified in the event of amendments, special meetings, etc.

Offers—or bids—may start arriving shortly after bidding documents are made available and continue up until a preestablished closing date. However, these bids cannot be opened and must be securely stored until the time and place indicated in the bidding documents. At that time, they are opened in public, often by a specially appointed bid opening committee. Basic, pertinent data such as price, delivery date, and the bidder's name and country are announced, but a winning bid is not identified at this time for two reasons: price is rarely the only determinant in selecting a supplier, and the prices indicated by bidders may not be fully comparable.

Module 7. Selecting Suppliers

In most public-sector systems, suppliers are selected by special committees convened for that purpose and chaired by a relatively high-level official. Procurement personnel may help with the paperwork, but the committees are responsible for examining, evaluating, and comparing the offers, and finally agreeing on the best one. In public-sector procurement, this is a strict process guided by evaluation criteria announced in the bidding documents in advance. International suppliers expect the selection process to adhere to the stated evaluation criteria, so problems are likely if the selection is based on ministerial privilege or anything other than the evaluation criteria.

After the best offer has been determined, the financial, commercial, and technical background of the apparent successful bidder (and one alternate) will usually need to be checked to make sure the company has the capacity and capability to perform the contract.

Approvals at higher levels of an organization or government are generally required before an actual award can be made. Unfortunately, bottlenecks that delay the delivery schedule are often seen in this step.

Module 8. Contracts

After the supplier has been selected, the contract needs to be prepared, signed, and awarded. Often, there is a time limit for obtaining signatures. This activity also includes deciding on payment methods.

The first responsibility for contract execution lies with the purchaser, which provides some type of payment guarantee to the supplier. Particularly in trade with developing countries, manufacturers usually do not enter an order into production until this payment guarantee is in place. Producers frequently have a backlog of orders for products in high demand (e.g., condoms), so quickly establishing the payment guarantee keeps the delivery date on track. The most prevalent guarantee is a commercial letter of credit (L/C) opened at a reputable international bank by the purchaser in favor of the seller. The purchaser deposits money in the bank to "collateralize" the L/C; the bank holds it until the seller provides documentary evidence that it has complied with the terms and conditions of the L/C. More information about L/Cs and payment methods can be found in Supplementary Topics, Section C: Letters of Credit.

Phase III: Performance

In the performance phase of the RH supply process, the procuring entity monitors the supplier's performance, including arranging for preshipment inspection of goods, customs clearance upon arrival at the port of entry, and delivery to the receiving warehouse.

Module 9. Contract Performance and Monitoring

Contracts for contraceptives may require independent inspection of the goods at the supplier's facility when they are ready for shipment. This helps to ensure that incoming products are in good condition, packaged and labeled properly, and are being supplied in the correct quantities. For condoms, a sample is drawn and sent to an independent laboratory for quality testing as well. Condom testing discourages marginal suppliers from providing poor-quality products that malfunction during use. For more information, please refer to WHO's *The Male Latex Condom: Specification and Guidelines for Condom Procurement*[4] and to Supplementary Topics, Section I: Product Inspection and Testing.

[4] **World Health Organization (WHO), United Nations Population Fund, Joint United Nations Programme on HIV/AIDS. *The Male Latex Condom: Specification and Guidelines for Condom Procurement*. Geneva: WHO; 2003. Available at: http://www.who.int/reproductivehealth/publications/family_planning/9241591277/en/.**

One of the ways contraceptive purchasers can enforce QA requirements is by requiring a Certificate of Clean Findings as part of the L/C evidence mentioned above. If the supplier cannot provide the required certificate for the bank, the bank will determine that it has not fulfilled the terms and conditions and will not release the payment.

Module 10. Delivery of Goods

Public-sector contraceptives are normally shipped via ocean unless the supply source is close enough for trucking. Both of these options are far less expensive than air, which is usually reserved for emergency situations.

At the port of entry, goods are inspected for damage, and, in the case of contraceptives and pharmaceuticals, their regulatory licensing status is appraised. The procuring entity may hire a customs clearance agent to carry out necessary paperwork and obtain a release from customs. When this is not accomplished within a few days, demurrage (storage) charges are applied by the port authority, which can add up to significant amounts.

Upon release from customs, it is up to the purchaser to transport the goods to its own warehouse. Some customs clearance agents will make this arrangement, and sometimes a local representative of the supplier will do it. In most cases, the purchaser sends its own trucks or hires private transport.

Once delivered to the initial warehouse, personnel perform a receiving inspection, confirming that all goods are present according to the accompanying packing lists, are in good condition, and that product names and expiry dates are clearly marked.

E. Issues That Create Significant Delays and Other Problems in the Supply Process

This section identifies some of the common problems that occur in the supply process that can delay procurement and create product stock-outs. The *Toolkit* module(s) where additional information can be found on ways to address each problem is noted in parentheses.

1. Government Policy vs. Practical Application

a. Blanket Policy Devolving Procurement to Regional and Local Facilities (Module 3)

- ***Significance:*** Centralized procurement is a better option for contraceptives because it offers economies of scale and allows for better management of national stocks. In addition, contraceptives (in program quantities) are usually imported, requiring skill and knowledge that is not commonly found below the central level.
- ***The result:*** Contraceptives purchased at regional and local levels can be expensive and often out of stock due to weak management. RH program personnel may want to fight for centralized procurement of contraceptives as an exception to any blanket policy (decentralized supply is much more appropriate for pharmaceuticals, including those used in RH programs).

b. Procurement Rules, Policies, and Standard Bidding Document Clauses That Fail to Take Into Consideration the Special Nature of Contraceptives and Pharmaceuticals (Module 6)

- ***Significance:*** Issues of concern when purchasing machinery and equipment (e.g., spare parts) do not apply to contraceptives and pharmaceuticals.
- ***The result:*** Contracts without appropriate quality protections; confusion and/or protest on the part of bidders, leading to delayed delivery or cancellation of the bid.

c. Government Rules That Limit Financial Transactions to the Country's National Bank (Module 4)

- ***Significance:*** It may be impossible to open a commercial L/C that will be honored in another country.

- ***The result:*** Cancellation of the contract due to lack of compliance on the part of the purchaser.

d. Blanket Government Regulations Prohibiting Cash in Advance as a Payment Modality (Module 4)

- ***Significance:*** The rule is at odds with United Nations agency requirements.
- ***The result:*** Option of purchasing contraceptives through UNFPA is eliminated unless a variance can be arranged (which usually takes a good amount of time).

e. Blanket Taxation on Imports (Module 4)

- ***Significance:*** Takes money from one government pocket (public health) and puts it into another (general fund).
- ***The result:*** The number of clients an RH program can serve will be reduced.

f. Requiring That Certain Procurement-Related Activities Be Handled by a Different Ministry (Module 6)

- ***Significance:*** Once out of the hands of the procuring entity, it is impossible to control timing. The procuring entity uses websites, bulletin boards, and newspapers for the bid announcements in order to make sure the invitation reaches as many potential bidders as possible.
- ***The result:*** It is almost impossible to comply with good public-sector procurement policy that requires that all announcements of an opportunity to bid appear at the same time; bidders can lodge valid complaints that will probably delay the procurement process.

g. Mandatory Bidding Document Clauses (Approved at Ministerial Level) That Do Not Represent Normal Operating Procedures or the Actual Situation (Module 6)

- ***Significance:*** Requirements to perform in a certain way are embodied in the bidding documents.
- ***The result:*** Bidder protest and delayed procurement.

h. Government Hierarchy Rather Than Familiarity With a Specific Bid Requirement Determines the Chairperson for Pre-bid Meeting (Module 6)

- ***Significance:*** The chairperson controlling the meeting is unlikely to understand pertinent issues or the subject of the procurement.
- ***The result:*** Unproductive and sometimes poorly run pre-bid meeting; legitimate questions not answered promptly; confusion among potential bidders; potential for delaying the procurement process.

2. Program-Level Decisions

a. Deciding to Use a Procurement Agent Without Someone on Staff Who Knows What Should Be Happening (Module 3)

- ***Significance:*** Someone needs to monitor the agent's performance.
- ***The result:*** Potential for oversights; noncompliant processes; delays; less than the best supply contract; money wasted (fees payable to the agent).

b. Failure to Take Into Consideration Warehouse Capacity When Scheduling Shipments (Modules 4 and 5)

- ***Significance:*** Inability to plan space for the shipments; creating a lost opportunity to solve problems before they occur.
- ***The result:*** Overcrowding or having to pay for additional space in another facility.

c. Accepting Donations (or Bargains) on Goods That Are Not Needed (Module 4)

- ***Significance:*** Excess goods fill up warehouse space needed for other products.
- ***The result:*** Overcrowding or having to pay for additional space in another facility.

d. Specifying and Planning on a Delivery Date Without Taking Into Consideration the Normal Timeline for Procurement – 12 Months (Modules 4 and 5)

- ***Significance:*** False expectations.
- ***The result:*** Potential for stock-outs and no plan in place to cope with the realities of the stock situation; lost opportunity to prevent problems before they happen.

e. Failure to Act on Information and Constraints Uncovered During Planning Work That Will Affect What is Possible and How Long the Supply Process Will Take (Module 5)

- ***Significance:*** Flawed expectations.
- ***The result:*** Later deliveries; potential for stock-outs.

3. Financial, Budgeting, and Accounting

a. Accounting System Not Showing Outstanding Commitments (Module 4)

- ***Significance:*** Overstated line item balances.
- ***The result:*** Some managers will use up funds that will be needed later.

b. Manager's Failure to Take Into Consideration a Likely Time Frame for Payment Obligations (Module 5)

- ***Significance:*** Funds may not be available when payment obligations are due.
- ***The result:*** Delayed delivery; cancelled contract.

c. Lack of Provision for Access to Ready Cash for Minor Expenses (Module 4)

- ***Significance:*** Alternative arrangements will be needed for:
  - Postage to send bidding documents to potential bidders located outside the immediate area of the procurement office.
  - Car fare to transport personnel on procurement-related business.
  - Minor expenses related to port clearing.
- ***The result:*** Delays while alternative arrangements are being made add up to later delivery (and in the case of port clearing, a risk of demurrage charges), thus much higher costs.

d. Forgetting to Add in Associated Costs and Fees When Developing a Budget (Module 4)

- ***Significance:*** Costs and fees will need to be paid whether they are budgeted or not.
- ***The result:*** Not enough money to cover planned procurement; reduction in quantities/shortages; using inappropriate prices for cost estimates; not understanding what is and is not included in representative prices.

e. Failure to Provide for Possible Currency Value Fluctuation When Budgeting for Goods That Are Likely to Come From a Foreign Source (Module 4)

- ***Significance:*** Potential for increased cost.
- ***The result:*** Not enough money to cover entire commodity requirement; reduction in quantities/shortages.

f. Funding Released Quarterly or Monthly (Module 4)

- ***Significance:*** Funds will need to be accumulated in anticipation of future payment obligations. Requires very careful timing of procurement activity so contract signing does not occur before enough money is available to cover the payment guarantee.
- ***The result:*** Potential for delayed delivery and stock shortages.

4. Bidding Documents

a. Not Including Special Handling Requirements in Contracts and Shipping Instructions (Module 6)

- ***Significance:*** Goods may end up on an unprotected deck of a cargo ship in rough waters.
- ***The result:*** Heat and moisture can damage oral contraceptives, condoms, etc.

b. Lack of Marking Instructions for Intermediate Boxes (Module 6)

- ***Significance:*** Name of product and expiry date may be missing from cartons.
- ***The result:*** Inefficient storage and stock handling; incorrect items delivered to service sites.

c. Bidding Documents Not Listing Exactly What Will Be Required for Entry Into the Purchaser's Country (Module 6)

- ***Significance:*** If proper documentation is not presented, shipment can be held at the port, returned, or destroyed.
- ***The result:*** Stock-outs—a good example of how a small oversight in bidding documents can turn into a supply disaster.

d. Last-Minute Edits to a Bidding Document Clause That Are Not Carried Through to the Corresponding Clauses in Other Sections (Module 6)

- ***Significance:*** Can change intended meaning.
- ***The result:*** Confusion; need to amend bidding documents and/or extend the closing date; later deliveries.

e. Bidding Document Clauses That Include Commitments the Procuring Entity Is Not at Liberty to Make and Cannot Support (Sometimes Seen With Regard to Regulatory Licensing) (Module 6)

- ***Significance:*** False expectations on the part of bidders.
- ***The result:*** Confusion; protest; later deliveries.

f. Bidding Documents That Require Samples of Pharmaceuticals and Contraceptives Be Submitted With Bids (Module 6)

- ***Significance:*** Products to examine and test at extra time and cost.
- ***The result:*** Samples of these products will not be representative of quality at a future point in time; however, a simple visual inspection can be useful to weed out potential suppliers that submit obviously inferior products (e.g., in oily or dirty packaging).

5. Interministerial/Interdepartmental Coordination

a. Lack of a Defined Chain of Authority (Module 5)

- ***Significance:*** Procurement personnel need to know where to look for decisions and advice.
- ***The result:*** Delayed production of bidding documents, etc.; later delivery dates.

b. Slow Approvals (Module 5)

- ***Significance:*** Procurement process cannot advance without required approvals.
- ***The result:*** Offers may expire while waiting for approval; extensions must be arranged, and the whole procurement process will be delayed, leading to later delivery and possible stock-outs.

c. Letter of Credit Copies Not Made Available to Procurement Staff by the Finance Unit (Module 4)

- ***Significance:*** Omissions or mistakes on the L/C not detected and corrected.
- ***The result:*** Costly later correction; L/C may not be useful as a means to ensure product quality.

d. Government "Short List" (of Service Providers) Does Not Include Appropriate Contraceptive Inspection and Testing Firms (Modules 5 and 6)

- ***Significance:*** Separate, lengthy bid process is required to establish them.
- ***The result:*** Delayed supply process; lack of authorization to contract for associated services, such as inspection and testing.

e. Minimal Advertisement of the Invitation for Bids (Module 6)

- ***Significance:*** Potential bidders are not aware of the opportunity so there is not enough competition to validate the bidding.
- ***The result:*** Bidding exercise may need to be cancelled and rerun, leading to later deliveries; potential for stock-outs.

6. Evaluation Committees

a. Failure to Check the References of the Apparent Winning Bidder (Module 7)

- ***Significance:*** Information provided by the bidder may not be entirely truthful.
- ***The result:*** Possibility that the supplier will not perform adequately; late deliveries; poor quality.

b. Lack of Knowledge About How to Read Bidding Documents (Module 7)

- ***Significance:*** Bidding documents contain all requirements about the goods, the bidder's eligibility and qualifications, and describe how evaluation and selection will take place.
- ***The result:*** Faulty interpretation leading to erroneous judgment and potential protests lodged by unsuccessful bidders; delayed procurement; possible cancellation of the bid.

c. Misunderstandings About Interpreting Common Phrases Used in Procurement (Module 7)

- ***Significance:*** Used in deciding if the bidder is qualified to perform the contract.
- ***The result:*** Potential error in selection of the winning bid; erroneous award; potential protests lodged by unsuccessful bidders; delayed procurement; possible cancellation of the bid.

d. Delay in Identifying a Winning Bid (Module 7)

- ***Significance:*** Bidders will need to be asked to extend the expiry date of their offers and bid securities; negative impact on the timeline.
- ***The result:*** Later delivery; risk of stock-outs; poor reputation for the next round of bidding.

7. Stakeholder Perception

a. Misunderstanding the Time Frame Required for Procurement (Module 5)

- ***Significance:*** Stakeholders are often in some position of power as funders and contributors to RH programs, so their opinions matter.
- ***The result:*** Negative impact on public procurement; unnecessary time and energy spent on helping peripheral individuals understand that public procurement requires at least 12 months from initiation to delivery and that "fault" cannot be tied to the efforts of any single office, as many players and situations have parts to play (the procurement staff itself cannot control, for example, how long an approval at the ministerial level might take).

F. Summary of Challenges

Policymakers should be aware of these challenges and do everything in their power to create policy that will overcome them. The following summarizes the key challenges found in each of the ten elements of the RH supply process.

1. Defining Reproductive Health Supply Requirements

- Ensuring the quality of the information gathered and the forecasts generated.
- The budget available for contraceptive procurement often drives procurement, rather than the other way around.

2. Specifications

- Obtaining or crafting comprehensive specifications in the format and technical language of the relevant industry (e.g., contraceptives, pharmaceuticals, condoms).
- Providing a clear, correct description of all regulatory requirements, including those of the relevant NRA.
- Ensuring that technical specifications are product neutral through the use of generic terms and relative characteristics.

3. Assessment of Procurement Options

- Understanding the options for procurement and the implications of each option.
- Honestly appraising the capabilities and environment of each option, even if findings are politically unflattering.

4. Budget, Funding, and Procurement Requisition

- Developing reasonably accurate cost estimates for each item.
- Maintaining principles of good public-sector procurement.

5. Procurement Planning

- Recognizing and working around potential conflicts and constraints in the environment or system.
- Determining how long each step in the procurement cycle is likely to take.

- Coordinating the procurement schedule with funds-release dates.
- Coordinating delivery dates with warehouse capacity and inventory requirements.

6. Developing Bidding Documents and Inviting Offers

- Building adequate product quality protections into the bidding documents.
- Neutralizing potential problems with the use of appropriate bidding document clauses.
- Making sure that what the bidding documents say is what will actually happen, thus reducing the chance of bidder protest, which can lead to delayed delivery.

7. Selecting Suppliers

- Maintaining principles and procedures of good public-sector procurement: fair appraisal and evaluation of each offer, equitable comparison of all offers, and selection based on the lowest evaluated cost.
- Ensuring appropriate documentation and justification for selection and award.
- Ensuring that approvals are rendered without undue delay.

8. Contracts

- Ensuring that contracts contain the provisions necessary to obtain good-quality products and provide adequate protection against a supplier's lack of performance.
- Ensuring timely contract award.
- Ensuring timely contract payment arrangements.

9. Contract Performance and Monitoring

- Eliciting supplier commitment to take contract compliance and monitoring seriously.
- Proactively implementing contract performance monitoring by the purchaser.

10. Delivery of Goods

- Understanding and supporting customs clearance requirements so that the clearance process is completed in a timely manner.
- Ensuring proper inspection of goods upon receipt at the receiving warehouse.

G. Glossary and Acronyms

Agent	A supply term for an independent contractor authorized by a manufacturer to promote and sell the manufacturer's products within a designated geographic area. Often, an agent will contract to represent several manufacturers of noncompeting products.
AIDS	Acquired Immunodeficiency Syndrome.
Bid	A procurement term describing a written offer for a quantity of goods, works, or services at a stated price based on a technical specification and specific terms and conditions. Bids are submitted to an intending purchaser by an intending seller in response to an Invitation for Bids.
Bidder	An intending seller or supplier that submits a bid offering goods or services in response to an invitation or request for bids and offers.
Bidding documents	The written description and set of terms and conditions of an intended purchase that is circulated by the intending buyer to prospective sellers.
Bid opening committee	Committee of a minimum of three members that administers and oversees the opening of sealed bids.
Bid security	A financial instrument used to guarantee compensation to the prospective buyer for inconvenience and expense if a winning bidder rescinds its offer after the bid is closed and an award has been made to the bidder. Each bidder provides an amount stated in the bidding documents with its bid submission.
Brand/Brand name	The registered trademark name given to a specific product by its manufacturer.
Centralized procurement	The government owns, funds, and manages the supply chain for the public-sector health system. Procurement is conducted at the central level.

Commodity	Any piece of tangible property, supplies, or equipment that is the subject of a procurement activity.
Component	An important function or process that occurs within an element of the reproductive health supply process. Each module of the *Toolkit* focuses on one element.
Contract	An agreement entered into by two parties for the execution of a certain activity (e.g., sale and purchase, construction, service provision, etc.).
Contract performance monitoring	Tracking system developed by the purchaser that uses monitoring system key performance indicators to monitor the supplier's compliance with contract requirements.
Convertible currency	Currency that can be quickly bought and sold for other currencies. Commonly traded internationally.
Cost	What the purchaser ultimately pays for an item, delivered to its facility. Cost, not price, is used for budgeting.
Criteria	Specific points, standards, qualities, and/or requirements against which something is judged.
Current good manufacturing practice(s)	Manufacturers must employ technologies and systems which are up to date to the performance standards for pharmaceutical and medical device manufacturers established by the World Health Organization and many national governments. Includes criteria for personnel, facilities, equipment, materials, manufacturing operations, labeling, packaging, quality control, and in most cases, stability testing.
Customs clearance agent	A licensed professional agent appointed by an importer to clear a shipment (consignment) coming from abroad through the port and customs authorities. Also called a customs broker.
Decentralized procurement	Different levels of responsibility for procurement are handled by the provincial, district, municipal, or even the facility level.

Demurrage charges	Charges assessed against the consignee (purchaser) by a carrier, shipping agent, or customs agent for delay beyond the time allowed or agreed upon for unloading and/or removal of goods from port facilities.
Direct procurement	Purchaser contracts for goods directly with a manufacturer or its representative.
Documentary evidence	Being, consisting of, or contained exclusively in documents.
Efficacy	The capacity of a drug to produce scientifically proven therapeutic effects.
Element	One of the ten key operational, broad-based activities in the reproductive health supply process.
Eligibility (criteria)	Not excluded from competing for contracts in general by reason of nationality, debarment, lack of regulatory approval, etc.
Entity	A business and legal term to describe something that exists and functions as a separate and distinct body (e.g., a corporation, Ministry of Health, or committee).
Evaluated cost	An offered price adjusted for corrections, discounts, domestic preference, and usage factors.
Evaluation criteria	Basis for judgment (announced in bidding documents) that will be used to select the winning bidder.
Expiration (Expiry) date	The date beyond which the manufacturer will not guarantee the product.
Fast-track licensing	Regulatory licensing based on confidence in the quality of a product as evidenced by similar licensing in countries with stringent, highly respected regulatory authorities.
Financial threshold	Monetary division used to trigger an action or requirement. (Procurement method selection is often tied to financial thresholds.)

Forecast	To calculate beforehand.
Funder	Organization (or person) providing funds for a specific project, program, or purpose.
GNI	Gross national income.
HIV	Human Immunodeficiency Virus.
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use: Addresses how harmonization of technical guidelines and requirements for product registration might be achieved.
IDA Foundation	Claims to be the world's largest not-for-profit supplier of essential medicines and medical supplies to low- and medium-income countries. Established in 1972 in Amsterdam by a group of pharmacists.
Indirect procurement	Purchaser contracts for goods through an intermediary that has or will purchase directly from a manufacturer.
International supply service	An international agency such as the United Nations Population Fund that purchases standardized commodities in large quantities and supplies them to developing-country government institutions at cost plus a fixed fee.
Invitation for Bids	An invitation to manufacturers or contractors, through a bidding process, to submit a proposal on a specific product or service to be furnished or project to be realized.
Joint United Nations Programme on HIV/AIDS	Brings together the efforts and resources of ten United Nations system organizations in the AIDS response to help the world prevent new HIV infections, care for people living with HIV, and mitigate the impact of the epidemic.
L/C	Letter of credit: An arrangement by banks for settling commercial transactions; specifically, a written promise by a bank given to the seller in accordance with instructions (backed by a cash deposit) of the buyer to pay up to a given sum of

	money within a prescribed time limit when and if the seller presents specified documents that give evidence of its performance.
Manufacturer's (Bidder's) representative	A direct employee of a manufacturer with responsibility to promote the use of, provide information on, and sell the manufacturer's products. In some cases, the representative also facilitates importation. Sometimes the term "agent" is used to convey the same relationship.
Method mix	Mix of products used by the target population, expressed as the percentage that each method constitutes among all contraceptives used.
Missionpharma	Supplies generic pharmaceuticals and medical devices to governments, United Nations agencies, and nongovernmental organizations in developing countries.
NRA	National regulatory authority (same as drug regulatory authority): An independent government entity responsible for establishing procedures to ensure that medicines intended for use in the country are safe, potent, and effective.
Offer	Used interchangeably with "bid," "tender," and "proposal."
Organisation for Economic Co-operation and Development	An international organization helping governments tackle the economic, social, and governance challenges of a globalized economy.
Packaging	The primary wrapping and marking of a product.
Packing list	A schedule showing detailed packing information, including items and totals, number of units or items per box or crate, total number of boxes or crates with individual identification numbers provided, shipping marks, total volume of the cargo, weights and dimensions per box or crate, etc.
Parastatal	Self-supporting, quasigovernmental organization.
Phase	A natural division of the ten elements of the supply process into three sequential parts:

	program planning, procurement process, and contract performance.
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme: Two international instruments between countries and pharmaceutical inspection authorities dedicated to standardizing and ensuring current good manufacturing practices and inspections. Currently, it has 31 member countries, with the European Medicines Agency, the United Nations Population Fund, and the World Health Organization as partners/observers.
Prequalification (of manufacturer/ supplier/bidder)	A process of preapproving suppliers for participation in bids based on a judgment of reliability, technical competence, and financial stability.
Prequalification (of product)	A process of predetermining that a specific product (usually a pharmaceutical, device, or vaccine) of a specific manufacturer meets stated requirements.
Preshipment inspection	An inspection of manufactured goods ready for shipment undertaken by an internationally recognized inspection agency (such as Societe Generale de Surveillance).
Price	What the seller asks for an item.
Private procurement agent	Undertakes a procurement process on behalf of a procuring entity using competitive bidding procedures and may or may not select the winning bid.
Procurement cycle	The repeating sequence of steps in a procurement process, generally starting at the initial planning phase and ending at possession of the goods.
Procurement method	Process a purchaser uses to reach an agreement with a seller.

Procurement option	Approach to procurement: Direct or indirect, and several subdivisions of each are differentiated by who contracts with the original manufacturer (or its representative).
Procurement requisition	A document describing what is to be purchased and giving authority to do so.
Procurement unit	Individuals organized around procurement duties within a larger entity.
Product neutral	Specifications that use generic terms, relative characteristics, and performance requirements rather than brand names and superficial descriptions.
QA	Quality assurance. For more information, see Supplementary Topics, Section H: Product Quality Assurance.
Quantification	Process of estimating product quantities to supply adequate stocks according to standard medical and program guidelines.
Registration	A term used in regulating medicines, pharmaceuticals, and vaccines; exact usage varies from country to country. It is often synonymous with licensing, but it can mean simply that the particulars about a shipment are recorded as it enters a country.
RH	Reproductive health: A state of complete physical, mental, and social well-being—not merely the absence of disease or infirmity—in all matters relating to the functions and processes of the reproductive system. Reproductive health implies that people are able to have a satisfying and safe sex life and that they have the capability to reproduce and the freedom to decide if, when, and how often to do so; implicit in this last condition is the right of men and women to be informed and to have access to safe, effective, affordable, and acceptable methods of family planning of their choice, as well as other methods of their choice, for regulation of fertility.
Specification	A definitive description of the commodity to be procured.

Standard	Establishes the minimum level of performance and safety requirements for the product, and generally specifies methods of use when carrying out basic tests for quality verification. Standards are traditionally developed and published by international and national regulatory authorities or standards bodies.
Supplier	The party that transfers goods out of its own control to a named recipient.
Supply	Goods and services of a specific kind that are provided to businesses, public agencies, or directly to consumers.
Target population	The collection of individuals or regions that are to be investigated in a statistical study.
UNFPA	United Nations Population Fund: A semiautonomous United Nations agency working to ensure universal access to reproductive health, including family planning and sexual health, to all couples and individuals. Operates a global procurement service for public-sector purchasers of contraceptives and related products.
UNICEF	United Nations Children's Fund: A semiautonomous United Nations agency working for sustainable human development to ensure the survival, protection, and development of children. Operates a global supply service that contracts with manufacturers for large quantities of vaccine and other products which it then supplies in smaller quantities to individual clients in the public sector on a reimbursable, but not-for-profit basis.
United Nations	An international organization founded in 1945 after the Second World War by 51 countries committed to maintaining international peace and security; developing friendly relations among nations; and promoting social progress, better living standards, and human rights.

Visual inspection	A comparison of a product to written specifications (e.g., packaging, labeling, and marking instructions) that is performed without the aid of test instruments.
WHO	World Health Organization: The directing and coordinating authority for health within the United Nations system.
WHO prequalification	Included on the WHO list of prequalified medicines. WHO assesses quality, efficacy, and safety of specific medicines from specific manufacturers and accepts or rejects them for inclusion on its list. For more information, see Supplementary Topics, Section E: Prequalification.
World Bank	The World Bank Group offers loans, advice, and an array of customized resources to more than 100 developing countries and countries in transition.