



ASSESSING POLICIES AND PRACTICES THAT AFFECT CONTRACEPTIVE FINANCING AND PROCUREMENT

A REVIEW GUIDE

APRIL 2010

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CONTENTS

Acronyms	V
Introduction	I
Important Terminology and Concepts	2
Overview of the Assessment Guide	5
Methodology	9
Organization of the Guide	10
Overall Assessment Process	11
Assessment Questions for Understanding Policies and Practices Related to Procurement and Financing	17
Assessing Policies and Practices Related to Procurement	17
Assessing Policies and Practices Related to Financing	27
References	32
Appendices	
A. Glossary	
B. Sample Scope of Work	
C. Suggested Issues and Policies for Desk-Based Policy Audit	
D. Additional Resources	41
Boxes	
What Is Contraceptive Security?	
Basket Funding in Malawi	
3. Alternative Procurement in the Private Sector in Malawi	
4. Malawi's Assessment	
5. Ensuring Ownership	16
Figures	
The Policy Environment from Policy to Practice	
2. General Steps in the Procurement Process	3
3. Procuring and Financing Contraceptives: Summary of Major Steps	13
Tables	
I. Illustrative List of Key Informants	
2. Key Issues and Effects	
3. Government or Donor Entities That Procure or Donate Contraceptives	
4. Procurement Methods and Criteria	
5. Government Financing	
6. Historical and Future Financing for Contraceptive Methods and Commodities	29

ACRONYMS

CIB coordinated informed buying

CMS Central Medical Store
EDL Essential Drugs List
EHP Essential Health Package

ICB International Competitive Bidding

IPPF International Planned Parenthood Federation

KfW Kreditanstalt für Wiederaufbau

LICB Limited International Competitive Bidding

MOF Ministry of Finance
MOH Ministry of Health

MTEF Medium Term Expenditure Framework

NEDL National Essential Drugs List
NGO nongovernmental organization

OECD Organisation for Economic Co-operation and Development

PATH Program for Appropriate Technology in Health

PRSP poverty reduction strategic plan
PSI Population Services International
PSM Procurement and Supply Management

RHU reproductive health unit

SPARHCS Strategic Pathway to Reproductive Health Commodity Security

SWAp sector-wide approach
UNFPA U.N. Population Fund

USAID U.S. Agency for International Development

WHO World Health Organization

INTRODUCTION

Contraceptive security exists when every person can choose, obtain, and use high-quality contraceptives and condoms whenever they are needed. There are many essential elements to achieve contraceptive security. Foremost is the need for family planning and reproductive health programs—whether in the public or private sectors—to have efficient mechanisms to finance and procure contraceptives.

Over the past decade, the environment has changed in which family planning products and supplies are financed and procured. The emphasis in many countries has shifted from vertical, project-focused financing and procurement to integrated, coordinated approaches—often as a result of adopting sector-wide approaches, poverty-reduction strategies, and the Millennium

WHAT IS CONTRACEPTIVE SECURITY?

Contraceptive security exists when every person can choose, obtain, and use high-quality contraceptives whenever they are needed.

Development Goals. Within this new environment, alternative financing mechanisms—such as direct budget support, including basket funding (pooled financial resources)—have been developed for channeling and using government and donor resources for a single policy or expenditure program. More governments are using their own internally generated financing for public sector contraceptive needs and, critically, are assuming new responsibilities for contraceptive procurement.

Although such changes provide country governments with greater autonomy and ownership for contraceptive security, the policy and implementation challenges can affect the governments' ability to effectively and efficiently maintain health programs. Of particular importance is the consistent availability of high-quality health commodities. The functioning of a country's finance and procurement systems determines whether supplies are financed, procured, and delivered in a timely manner. Delays or inefficiencies in those systems can result in poor-quality products and in shortages and stockouts of essential health commodities.

The purpose of this guide is to help national governments, donors, and other key stakeholders improve the policy environment for contraceptive security and, in particular, the operational policies and practices for procuring and financing contraceptive supplies. This guide focuses on the public sector, but much of it may also be applied to the private sector, as well as financing and procuring other health commodities.

By addressing the operational policy and practices related to procuring and financing contraceptives, countries can achieve the following:

- More efficient and transparent processes and procedures for procurement and for financing.
- Greater government autonomy about procurement decisions.
- Improved planning for procuring and financing contraceptives.
- Improved program sustainability as a result of improved processes and procedures.
- Most important, more consistent availability of contraceptives for programs and their clients.

IMPORTANT TERMINOLOGY AND CONCEPTS

Operational policies are defined as the formal or informal rules, regulations, codes, guidelines, plans, budgets, and administrative norms that governments use to translate national laws and policies into programs and services (figure 1). For simplicity throughout this guide, operational policies will be referred to as "policies." It is important to remember that this guide does not focus on high-level national policies, such as a country's Reproductive Health Policy or its National Health Policy, except as those national policies help to frame the context for financing and procuring contraceptives.

Practices are defined as the systems or procedures used to implement a particular process. For this assessment guide, practices refer to those procedures and behaviors used to implement a policy or process for procuring and financing contraceptives. Sometimes practices serve as operational policies in the absence of any formal guidance. Ideally, governments formalize good practices with operational policies such as guidelines or regulations—instances in which policy follows practice.

Operational policy barriers are the policies, guidelines, regulations, or practices that may pose obstacles or challenges to commodity security as a result of misguided design or misguided implementation. Those barriers can include policies or practices that, while well-intentioned, may be (a) misguided or poorly understood, (b) difficult to implement or not implemented at all, (c) inconsistent with other policies or procedures, or (d) poorly resourced. In other situations, a lack of critical policies may exist all together, which would still be defined as an operational policy barrier.

FIGURE 1: THE POLICY ENVIRONMENT FROM POLICY TO PRACTICE

National-Level Policies and Laws

High-level policies that frame a national health care system, such as the National Health Policy

Operational Policies

Formal guidelines, regulations, and codes that implement and operationalize national policies such as Public Procurement Regulations or a National Drug Policy

Practices

Actual processes and behaviors that are used to implement operational policies or systems (Sometimes practices serve as operational policies in the absence of any formal guidance.)

Procurement is defined as the identification of suitable sources of supply and the acquisition of commodities according to a procurement plan—as economically as possible—within established quality standards (figure 2).

FIGURE 2: GENERAL STEPS IN THE PROCUREMENT PROCESS

PROCUREMENT PROCESS

Procurement Planning

- Selection
- Forecasting
- Specifications
- Budgeting and financing

Preparation of Tender Documents

- · Compliance with guidelines
- · Identifying qualified suppliers

Management of Bidding Process

- Transparency
- · Bid evaluators
- Award decision

Preparation and Signing of Contract

- Contract preparation
- · Legal compliance
- Payment
- Contract award

Contract Management

- Contract performance
- Shipments schedule
- Receipt of products

Quality Monitoring

- Pre-shipment batch testing
- Testing upon receipt of products
- Quality reporting system

Source: Family Planning Logistics Management/John Snow, Inc., 2000.

Financing is defined as the processes or mechanisms that provide resources for a program, service, or purchase. Financing in the context of this guide includes any source of resources for a country's contraceptive program—including donor funding. Financing also includes resources for the purchase or procurement of contraceptives. In a decentralized setting, financing of contraceptives may come from a district or province, depending on the country context.

OVERVIEW OF THE ASSESSMENT GUIDE

This guide will provide governments, donors, and other relevant stakeholders with a framework to assess the policy environment for procuring and financing contraceptives. The guide examines policies and practices to identify whether they are supporting or hindering the performance of such financing and procurement.

A country's finance and procurement systems determine whether supplies are financed, procured, and delivered in a timely manner. Supportive and functioning policies related to procuring and financing contraceptives provide an enabling environment and, when implemented effectively and efficiently, serve as the foundation for the effectiveness of those systems. Although tools and approaches have been developed to address challenges related to other aspects of contraceptive security, few address in detail the necessary policies and practices.

Analyzing the policy environment related to procuring and financing contraceptives can help determine the root causes of a health system's poor performance and can identify opportunities for improvement. This guide can be used as a diagnostic and monitoring tool to accomplish the following:

- Understand the policy environment related to procuring and financing contraceptives in a country.
- Identify existing policy barriers that may be hindering contraceptive security.
- Improve procurement policies and practices that affect contraceptive financing and procurement.
- Plan a smooth transition from donor-procured commodity support to government-financed or basketfunded commodity procurement by government agencies.
- Improve implementation of policies where the practice does not match the policy.
- Develop evidence to support advocacy for increased financing of contraceptives or for more efficient financing and procurement mechanisms.
- Monitor how financing and procurement policies are implemented.

More important, this guide is about both policies and practice and their implementation. Although countries may have well-designed policies, they may not be implemented appropriately (strictly, correctly, fully) or efficiently. This guide thus examines the prescribed procurement or the financing policies and procedures or both to determine where bottlenecks exist and which specific operational aspects should be addressed to improve the situation. Alternatively, if countries lack clear policies or guidelines, it is important to determine (a) how decisions are, nonetheless, made; (b) which key actors are involved in the decisionmaking process; and (c) whether additional or modified policies are needed to address operational shortcomings.

By examining the rules, regulations, guidelines, and practices that governments use to translate laws and polices into program implementation, one can gain a better understanding and appreciation for the challenges or barriers to financing and procuring a country's contraceptive needs.

HOW CAN THIS GUIDE BE USED?

The environment in which family planning products and supplies are procured and financed has changed over the past 10 years, and each country has its unique issues. This guide has been developed to be adapted in response to those varying settings and purposes. For example, it can be used as a diagnostic tool (a) to help anticipate and address issues prior to a change in policy, (b) to monitor how policies are implemented, and (c)

BASKET FUNDING IN MALAWI

In late 2004, Malawi began using the sector-wide approach (SWAp) basket funding mechanism for its health sector. Through an examination of policies and procedures related to financing and procurement within the SWAp, the assessment identified an unintended consequence: current and anticipated drug stockouts. Stockouts of health commodities can result from the lengthy, structured procurement procedures and process reviews required under many SWAp agreements; the risk is increased by government personnel's unfamiliarity with the new procedures. In 2006, the procurement process in Malawi for injectable contraceptives lasted longer than the months of supply available, leading to the need for an emergency donation of Depo-Provera by USAID.

Source: USAID | Health Policy Initiative and USAID | DELIVER PROJECT.

to inform advocacy that will highlight ways to improve procuring and financing contraceptives.

In anticipation of a major policy change, this guide can help map out the intended implementation of the policy shift and can identify implications for procuring and financing contraceptives. The guide can help plan a smooth transition and can ensure that reproductive health procurement and financing are adequately considered in the new or changing policy. Examples include the following:

- A decision to make all public sector contraceptives free to clients.
- The devolution of procuring or financing contraceptives to decentralized administrative entities as part of health sector reforms.
- A government shift to increased use of internally generated funds that will finance procuring contraceptives.
- A country considers using basket, or pooled, funding to procure health commodities.
- As countries integrate health systems, reproductive health stakeholders consider using this guide to
 identify potential threats to contraceptive financing and procurement and to advocate for policies,
 guidelines, procedures, and so forth that will address those threats as a priority.

WHO ARE THE INTENDED "OWNERS" OF THE ASSESSMENT PROCESS AND THE OUTCOMES?

Although a Ministry of Health (MOH) is an obvious owner and beneficiary of the overall process that this guide supports, multiple owners must, in fact, identify the need for the assessment's application, as well as champion the resulting recommendations. Donors and implementing partners can help identify the need to assess the financing and procurement of contraceptives, and they can support implementation of the assessment and its resulting recommendations.

Findings and recommendations of the assessment that relate to specific reproductive health and family planning issues will fall within the mandate of the reproductive health unit of the MOH. It is thus critical that the reproductive health unit or its equivalent helps to drive the assessment process. At the same time, procurement-related findings and recommendations tend to relate to broader, more system-wide issues and, therefore, fall within the remit of an MOH procurement unit or an equivalent elsewhere in the government (e.g., a central procurement unit). Findings related to financing, such as budget planning and disbursements of funds within the government, will necessarily involve the Ministry of Finance (MOF).

Bringing together those important stakeholders can be not only one of the challenges of this approach, but also one of the strengths. In the linking of the two topics—procuring and financing—and the respective stakeholders at an operational level, this approach allows users (a) to identify specific problems, (b) to understand the important interrelationship between procuring and financing, and (c) to lay the foundation for collaboration to address critical issues.

WHAT SKILLS AND RESOURCES ARE NEEDED TO CONDUCT THE ASSESSMENT?

Experience indicates that application of this guide requires substantial expertise and understanding of procuring and financing. For the procurement-related aspects of this assessment, it is important to have someone with a general knowledge of the procurement process and components of related laws, as well as an understanding of who are the major stakeholders. For financing, it would be valuable to have someone familiar with the budgeting process and the major financing mechanisms. Those skills may be available within an MOH or MOF or both, or this expertise may need to be obtained from external sources. In addition to some expertise in procuring and financing, the assessment team should also have a general understanding of a country's policy environment related to procuring and financing contraceptives, and be able to quickly assess key issues and adapt the guide and assessment methodology to a country's context.

The assessment team members should have competencies in research and analysis. Because this assessment involves reviewing public sector policies and assessing gaps in or challenges posed by those policies, the assessment team must be able to draw conclusions and to make recommendations using multiple and various information sources—both policy documents and interviews with key informants.

The assessment team can engage in-country consultants or implementing partners with this expertise or both. Regardless, it is critical that MOH counterparts with mandates for reproductive health and procurement are involved in the entire process. As mentioned earlier, it may also be critical to involve other government entities in the design and implementation of the assessment.

In addition to having members with expertise, the team will find it helpful to refer to key reference documents and resources to help determine best practices related to procuring and financing contraceptives. A list of resources can be found in appendix D.

IS THIS GUIDE INTENDED ONLY TO EXAMINE PROCURING AND FINANCING CONTRACEPTIVES?

The guide is intended to provide a framework and approach to address those procuring and financing issues that affect the availability of contraceptives in public health programs. However, with some exceptions, the issues of procuring and financing that relate to contraceptives are likely to relate to other health commodities as well. For example, an MOH procurement unit may be required to use the same standard operating procedures for all health commodities when basket funds are involved, and higher-level public sector procurement reforms will likely apply across the board to all government procurements of goods. Therefore, the use of this guide is not limited to contraceptive commodities; it can be broadly applied to malaria drugs, mosquito nets, HIV test kits, antiretrovirals, and tuberculosis drugs, among others.

CAN THE GUIDE BE USED FOR PRIVATE SECTOR AND NONGOVERNMENTAL ORGANIZATION (NGO) PURPOSES?

The focus of this guide is to examine financing and procurement in the public sector. However, in doing so, one must understand and consider other sources of supply as they relate to and affect the public sector. The next box describes the effect of Malawi's policy permitting districts to procure contraceptives and other commodities from local commercial suppliers in the event of a public sector stockout of those items. As this example demonstrates, although the policy may make sense in theory, the application of this guide revealed reasons that the policy was not realistic.

HOW DOES THIS GUIDE RELATE TO OTHER TOOLS AND APPROACHES?

Several tools and approaches exist to address challenges related to contraceptive security or to public sector procurement more generally. This guide builds on and complements existing tools by providing an in-depth focus that specifically links financing and procuring of contraceptives.

ALTERNATIVE PROCUREMENT IN THE PRIVATE SECTOR IN MALAWI

If the Central Medical Store (CMS) in Malawi is out of stock of a particular drug or contraceptive, CMS can grant permission to a district to purchase that commodity from a local commercial source. In theory, districts seeking to procure commodities from a source other than CMS must follow the appropriate procurement laws and regulations. Typically, procurements at the district level will amount to less than US\$100,000, which allows districts to follow national procurement procedures rather than World Bank procurement procedures. National procedures stipulate that procurement entities must obtain three quotes for a commodity to be purchased.

Although districts can opt to procure commodities, they face numerous challenges to successfully procure commodities in what may be emergency situations:

- Human capacity in the health sector at the district level is already challenged by limited resources and competing health issues such as maternal mortality and HIV, leaving little "surge capacity" to procure commodities on short notice.
- Private sector sources for drugs and contraceptives are minimal, and volumes are limited.
- Even existing private sector sources do not have a consistent supply of commodities because of the unpredictable nature of local demand.

Source: USAID | Health Policy Initiative and USAID | DELIVER PROJECT, 2008, p. 16.

- Strategic Pathway to Reproductive Health Commodity Security (SPARHCS) is a tool to help countries develop and implement strategies to secure essential supplies for family planning and reproductive health programs. SPARHCS helps stakeholders understand the broad issues related to contraceptive security generally. Its use often identifies a need for more indepth analysis of high-priority issues, which frequently include financing and procuring commodities. For additional information, visit http://www.maqweb.org/sparhcs/.
- OECD Methodology for Assessment of National Procurement Systems.

This methodology helps stakeholders assess the performance of in-country procurement systems. The methodology includes a scoring system to help identify the strengths and weaknesses of a procurement system and to monitor progress and improvements over time. For additional information on the OECD procurement assessment methodology, visit http://www.oecd.org/dataoecd/1/36/37130136.pdf.

- World Bank Assessment of Agency's Capacity to Procure Health Sector Goods. This methodology focuses on an agency's capacity to procure health sector goods under World Bank–financed projects. The primary objectives of this assessment are to evaluate the capability of the procuring agency and the adequacy of procurement, thereby assessing risks and developing recommendations to address deficiencies. For additional information on the World Bank's Assessment of Agency's Capacity to Procure Health Sector Goods, visit http://web.worldbank.org/WBSITE/EXTERNAL/PROJECTS/PR OCUREMENT/0,,contentMDK:20105513~menuPK:84283~pagePK:84269~piPK:60001558~theSite PK:84266,00.html.
- Global Fund Procurement and Supply Management (PSM) Assessment Tool. This tool helps ensure that the procurement plan submitted by principal recipients for Global Fund grants comply with Global Fund procurement policies. For more information on the PSM Assessment Tool, visit http://www.who.int/hdp/publications/13ki6.pdf.
- Procurement Capacity Toolkit: Tools and Resources for Procurement of Reproductive Health Supplies. This toolkit, developed by PATH (Program for Appropriate Technology in Health), targets in-country stakeholders responsible for the procurement of reproductive health supplies. Organized according to the key elements of the procurement process, it provides resources for customized, on-the-job training in 10 learning modules. For additional information and the complete toolkit, visit http://www.path.org/publications/details.php?i=1652.

METHODOLOGY

Both quantitative and qualitative data are required for assessing the environment for financing and procuring contraceptives. The assessment process outlined in this guide includes four parts:

- Desk-based review and policy audit. A desk-based review and a policy audit of country documents
 are used to inventory all policies, regulations, and guidelines that may affect procuring and financing
 health commodities, particularly contraceptives.
- Process map. This exercise outlines the steps involved in procuring and financing contraceptives and
 the stakeholders who develop, implement, oversee, and monitor or who are otherwise affected by the
 pertinent policies and regulations.
- **Key informant interviews or discussion groups or both.** These interviews and discussions help to determine if the desk review and process map are realistic. They also serve to
 - □ Clarify the existence of and identify the barriers and gaps in relevant policies and practices.
 - □ Compare policies as designed and intended to be implemented to actual perception of the policies and practices.
- Identification of issues and recommendations. The recommendations that result from this
 analysis describe strategies to improve the policies and implementation of policies for procuring and
 financing contraceptives.

ORGANIZATION OF THE GUIDE

This guide is organized in three main sections:

- 1. **Overall Assessment Process.** This "how to" section walks users through the entire process, describing steps in the analysis, as well as providing tools, resources, and references.
- 2. Assessment Questions for Understanding Policies and Practices Related to Procurement and Financing. This section provides a series of questions and tables to guide the data collection process. The questions are *illustrative* in nature and should be modified to the country context. The questions and topics also include factors that should be considered in decentralized settings. Questions noted with an asterisk are those that can likely be answered through the desk-based review and policy audit.
- 3. **Appendices.** This section provides useful resources, including a glossary of key terms (appendix A), a sample scope of work for the assessment (appendix B), and the recommended policies to consult for the desk-based review and policy audit and as preparation for the key informant interviews (appendix C).

OVERALL ASSESSMENT PROCESS

This "how to" section walks users through the entire process, describing important steps in the activity and providing tools, resources, and references.

1. Determine the need for the assessment.

As described earlier, an assessment of procuring and financing contraceptives may be prompted for several reasons: (a) a major policy change, (b) reports of repeated contraceptive stockouts, (c) a follow-up to a more general contraceptive security assessment, or (d) support for monitoring of and advocacy for improvements in procuring and financing contraceptives.

According to the identified need for the assessment, stakeholders can clarify the objectives of the assessment and can develop a *scope of work* (appendix B) based on the program and the categories of health commodities to be considered.

MALAWI'S ASSESSMENT

Key Malawi stakeholders participated in two activities in which challenges related to procuring and financing commodities were highlighted (a workshop on regional reproductive health commodity security in Tanzania and a SPARHCS assessment in Malawi). Stakeholders determined that a more in-depth assessment of procuring and financing contraceptives would support Malawi's contraceptive security strategy and efforts to improve contraceptive security.

Source: USAID | Health Policy Initiative and USAID | DELIVER PROJECT, 2008.

2. Plan for the assessment.

- a. Engage key stakeholders to determine interest in and timing of the activity. Pay particular attention to ensure the availability of key government stakeholders with responsibilities for reproductive health, particularly those involved in the financing and procurement of contraceptives. Recruit or identify key staff members for the assessment. (See appendix B for qualifications to consider.)
- b. Secure financing for assessment costs including consultants, travel, accommodations, logistics, and local transportation.
- c. Obtain written authorization (if needed) for team members to visit facilities.

3. Carry out preparatory research.

a. Conduct a desk-based review and policy audit to inventory policies, regulations, and guidelines and other relevant information that may affect procuring and financing health commodities, particularly contraceptives. (See appendix C for suggested issues and policies for the policy audit.)

In many cases, the assessment team can collect a significant amount of information from existing documents and resources. The questions in section III that may be addressed as part of the desk-based review and policy audit are indicated by an asterisk (*). Information collected from this step can accomplish the following:

- Identify the specific processes and procedures most relevant to the issues being assessed.
- Identify relationships among key actors and agencies involved in or affected by the policy process.
- Highlight policies or questions that will need further clarification and verification with in-country stakeholders.

- b. *Create a process map* to outline the steps involved in procuring and financing contraceptives, and identify the stakeholders who develop, implement, oversee, and monitor or are affected by the pertinent policies and regulations.
 - Figure 3 describes the major steps of procuring and financing contraceptives, with a provision to note the specific agencies and policies that are pertinent to each step. This diagram can help assessors and stakeholders understand the relationship between procurement and financing and can identify the key informants and the key policies that may affect procuring and financing contraceptives.

FIGURE 3: PROCURING AND FINANCING CONTRACEPTIVES: SUMMARY OF MAJOR STEPS

FINANCING & PROCUREMENT OF CONTRACEPTIVES

Summary of Major Steps

Procurement Steps	Financing Steps	Responsible Agency	Operational Policy
Select Drugs			
Register Drugs			
Quantification & Forecasting Develop & Approve Procurement Plan	Budgeting & Financial Commitment		
Prepare & Issue Tender			
Evaluate Tender & Select Supplier			
Issue Contract & Establish Payment Process			
Pre-shipment Inspection/Testing	Disburse Funds		
Customs Clearance Receipt & Inspection			

4. Conduct key informant interviews or focus group discussions.

a. Key informants will be identified, in part, through the process mapping exercise. Table 1 is an illustrative list of key informants.

TABLE I: ILLUSTRATIVE LIST OF KEY INFORMANTS

KEY INFORMANTS

Ministry of Health—Reproductive Health Unit

Ministry of Health—Finance Unit

Ministry of Health—Procurement Unit

Ministry of Health—Planning Unit

Ministry of Health—SWAp Secretariat

Central Medical Store

Ministry of Finance

Revenue Authority

National Drug Quality Control Lab

Pharmacy Medicines and Poisons Board

Office of Director of Public Procurement

Procurement agents

Donors and multilateral agencies (U.N. Population Fund, World Bank, U.N. Children's Fund, U.K. Department for International Development, U.S. Agency for International Development, Deutsche Gesellschaft für Technische Zusammenarbeit, and so forth)

Social marketing organizations

Nongovernmental organizations

Technical assistance providers

Regional and district-level informants

It may be important to garner input from subnational levels, particularly where financing, procurement, or both are decentralized. In engaging lower-level stakeholders, assessors can accomplish the following:

- Map out the effect of national policies at lower levels.
- Understand lower-level issues that may not have been considered in developing national policies.
- Determine if lower-level stakeholders are informed of key policies.
- Assess what is being said at the national and central levels.

- b. Section III provides illustrative questions to guide the key informant interviews and focus group discussions. Through interviews and discussions, the assessors can accomplish the following:
 - Continue collecting and reviewing key documents.
 - Verify information collected through the policy audit, collect new information where data were not available, and solicit feedback on how the policy environment can be improved.
 - Clarify the existence of and identify barriers or gaps in relevant policies and practices.
 - Compare policies as designed and intended to be implemented against policies in practice and perception.

Although it is important to engage high-level authorities, it is also important to engage other relevant stakeholders, including those with more day-to-day responsibilities for procurement in particular. Their involvement will help determine whether the policies and procedures related to procurement are being effectively implemented and whether informal, undocumented practices are affecting procurement effectiveness.

5. Analyze findings.

One of the first steps of the analysis is to identify issues that are rooted in policies and implementation and that have the greatest effect on the availability of contraceptives, product quality, and efficient and effective use of resources. In other words, issues that come up during the assessment pertaining to lack of resources or lack of human capacity for procuring contraceptives, for example, are not within the scope of this type of assessment. During the preparatory research and throughout the assessment, use of table 2 can help highlight key issues, organize findings, and generate recommendations.

TABLE 2: KEY ISSUES AND EFFECTS

Issue affecting procuring or financing contraceptives or both	Responsible agency	Effect	Recommendation

6. Build consensus, garner ownership, and plan for implementation.

- a. Briefings and feedback meetings to share and review initial findings and observations with key informants can help the assessment team to identify inconsistencies, to obtain clarification from stakeholders, to further determine if perceived circumstances are realistic, and to build consensus on critical findings. Additionally, the meetings provide an opportunity for ongoing awareness raising to help stakeholders understand the important relationships between procurement and the financing of functions and policies.
- b. Once feedback is garnered, the assessment team can accomplish the following:

- Summarize the findings.
- Diagnose strengths and weaknesses.
- Develop concrete recommendations and next steps.
- Determine which stakeholders will own (take on) the key next steps.
- Identify opportunities to align recommendations and actionable next steps into existing strategies or work-planning processes.
- Identify resources needed to support critical recommendations and next steps.
- Develop key indicators that can be routinely monitored to help stakeholders track progress.

NOTE: Again, this step should be participatory and should engage those stakeholders needed to ensure consensus.

ENSURING OWNERSHIP

Although an MOH is an obvious owner and beneficiary of the overall process that this guide supports, there are, in fact, multiple owners that must champion the resulting recommendations.

Assessment findings and recommendations that relate to specific reproductive health and family planning issues will fall within the mandate of the reproductive health unit of the MOH. It is thus critical that the reproductive health unit or its equivalent helps to drive the assessment and implementation process.

At the same time, procurement-related findings and recommendations tend to relate to broader, more system-wide issues and, therefore, fall within the remit of an MOH procurement unit or an equivalent elsewhere in the government (e.g., a central procurement unit).

Findings related to financing, such as budget planning and disbursements of funds within the government, will necessarily involve the Ministry of Finance.

Bringing together those important stakeholders can be not only one of the challenges of this approach but also one of the strengths. In the linking of the two topics—procuring and financing—and the respective stakeholders at an operational level, this approach allows users (a) to identify specific problems, (b) to understand the important interrelationship between procuring and financing, and (c) to lay the foundation for collaboration to address critical issues.

c. The assessment team should summarize the previously described activities in a final report and should disseminate the report to key stakeholders. Although the report and its dissemination are often considered the culmination of an activity, in reality, they are just the beginning. The expectation is that the report and its dissemination serve as the foundation and roadmap for implementation. Therefore, dissemination—step b—is critical to providing a concrete roadmap to help key stakeholders understand their roles and responsibilities and ensure they have the resources to take on the critical next steps.

ASSESSMENT QUESTIONS FOR UNDERSTANDING POLICIES AND PRACTICES RELATED TO PROCUREMENT AND FINANCING

ASSESSING POLICIES AND PRACTICES RELATED TO PROCUREMENT

Goal: Review the procurement process and procurement-related policies to identify challenges, problems, and barriers that affect the successful provision of health commodities, particularly contraceptives, to support program needs.

Background: Public procurement should be transparent and should provide value for money while safeguarding quality and public safety. Laws, policies, and practices can and do affect the purchase and quality of contraceptive commodities. This portion of section II focuses on the policies and practices related to procurement of health commodities, with a special focus on contraceptives and condoms. The questions that follow are to be used as a guide and are illustrative in nature.

Key areas: This portion of section II is organized according to the following key components of procurement:

- Context
- Product selection
- Product registration
- Quantification and forecasting
- Development of procurement plans
- Financial commitment and budgeting
- Preparation and issuance of tenders

- Quality assurance in the tendering and procuring process
- Tender evaluation and selection of supplier
- Issuance of contract and payment arrangements
- Preshipment inspection
- Customs clearance plus receipt and inspection
- Decentralized procurement
- Other issues: Challenges and opportunities

Points to keep in mind:

- Prior to completion of this portion of section II, it is important to determine the responsible authority
 for the key procurement functions. For example, the Drug Board within the MOH is likely to be
 responsible for drug registration issues. A country's Central Medical Store is likely to be responsible for
 procuring and distributing the public sector's drug supply. Similarly, the MOF may be in charge of both
 the taxes and the setting of subsidies and incentives for locally owned firms.
- Discussions surrounding procurement have the potential of being politically charged, and issues are often difficult to uncover. Stakeholders may feel that the information is proprietary or that they are under scrutiny and, therefore, are not able to candidly share critical information.

Expected outcome:

- Validation of the findings from the desk-based review and policy audit and determination of how
 policies and procedures are being practiced and how those serve as the basis for the process map
 (figure 3) that may help highlight any inefficiency in the current practices
- Clear understanding of the way procurement policies are being implemented and ideas of how to remove barriers that limit efficiency and effectiveness
- Discussions surrounding procurement have the potential of being politically charged, and issues are often difficult to uncover. Stakeholders may feel that the information is proprietary or that they are under scrutiny and, therefore, are not able to candidly share critical information.

In the following numbered items, the readers will occasionally find asterisks. The questions that may be addressed and can likely be answered as part of the desk-based review and policy audit are indicated by such an asterisk (*). Sometimes the asterisk may also indicate that the information may be found during the policy audit rather than during an interview.

A. CONTEXT

- 1. Collect information regarding the government or donor entities that procured or provided contraceptives for the country for the previous year's contraceptive commodity procurements. This information may be available in the RHInterchange (http://rhi.rhisupplies.org) and other in-country sources. The sample table (table 3) provides a framework for collecting this important procurement information while using the following categories of data:
 - *Commodity* is the contraceptive method or commodity procured for the public sector program.
 - Funding source is the source of funds for the procurement of the contraceptive method or commodity (e.g., government funds or donor funds).
 - *Quantity* is the number of units of the contraceptive method or commodity procured in the previous year's procurements.
 - *Unit price* is the unit price of the contraceptive method or commodity paid in the procurement (unit prices may be subject to confidentiality, depending on the supplier.)
 - *Procured by* is a description of the entity procuring the commodities. The Central Medical Stores or central procurement agency may procure on behalf of the public sector, or procurement may be done by a procurement agent such as the U.N. Population Fund.
 - Supplier is the actual supplier of the contraceptive method or commodity (e.g., Pfizer for Depo-Provera).

TABLE 3: GOVERNMENT OR DONOR ENTITIES THAT PROCURE OR DONATE CONTRACEPTIVES

Funding source	Quantity (units)	Unit price	Procured by ^a	Supplier
By method				
Government ^b				
U.N. Population Fund				
U.S. Agency for International Development				
U.K. Department for International Development				
Kreditanstalt für Wiederaufbau				
International Planned Parenthood Federation				
Population Services International or DKT International				
Other				

Note:

- a. Contraceptives can be procured either by the donating entity (e.g., USAID) or directly by the government or a third party. For example, a country may procure contraceptives with its own funding through the UNFPA as the procurement agent. In that example, the country government would be the funding source, and the contraceptives would be procured by the UNFPA.
- b. Government can refer to national, state, provincial, or other local authority.
- 2. Map out the key steps for procuring contraceptives for the public sector (from product selection to customs clearance). Use the sample process map (figure 3) as a guide:
 - Identify the national policies, guidelines, regulations, and funder requirements that govern the financing of this process.
 - Identify the principal organization responsible for implementing each key step in the process.
- 3. Frequently, getting a policy implemented requires cooperation among many organizations, from various levels, from different ministries, and even from different sectors. Which organizations must collaborate to ensure successful implementation of the procurement-related policies?

- 4. How do government procurement processes and practices for contraceptives compare to procurement processes and practices of other health commodities? For example, some commodities may be procured through a vertical program (e.g., antiretrovirals) while others are procured through basket funds.*
- 5. Describe the cycle times from product selection to customs clearance for the following:
 - a. Government-financed contraceptive procurements
 - b. Donor-financed contraceptive procurement
- 6. Do national procurement laws provide preferences for local suppliers or locally manufactured commodities or both? Are there exceptions to local procurement? What are the criteria for exceptions?**
- 7. What are the constraints and incentives to the commercial sector's ability to supply contraceptives to the public sector (e.g., drug authority registration, World Health Organization [WHO] prequalification, protectionism, and lack of commercial suppliers)?
- 8. What are the perceptions of specific groups regarding the effectiveness and efficiency of the national procurement-related policies (e.g., Reproductive Health Commodity Security committee, ministries, donors, multilaterals, parliamentary groups, regulatory groups, private sector and NGOs, health care providers, and civil society)?
- 9. Describe the structure and the human and financial resources and capacity for procurement within the MOH:
 - Does the MOH have a procurement unit?
 - a. What is the number of personnel?
 - b. What are the personnel's titles and capacity, generally (level of education, procurement training, and so forth)?
 - Is the central procurement agency/central medical store a parastatal organization or purely a government agency?
 - Is the central procurement agency well capitalized, or is it a trust? That is, does it have adequate financial resources to complete procurement requirements for the public sector?
- 10. What issues, if any, have arisen with the quality of contraceptives within the past 5 years?
- 11. What issues, if any, have arisen with testing procedures for contraceptives in the past 5 years?
- 12. What issues, if any, have arisen with the quality of essential drugs within the past 5 years?

B. PRODUCT SELECTION

- 13. Does the country have (a) an Essential Health Package for the public sector health system, (b) a National Essential Drugs List (NEDL), or (c) both?*
- 14. What are the policies, regulations, or practices that govern the process for adding drugs and medical devices to the NEDL or the public sector Essential Health Package or both?*
- 15. Which government agency is responsible for managing and updating the NEDL and public sector Essential Health Package?*

- 16. Are contraceptives included in the country's NEDL or public sector Essential Health Package or both? If yes, which contraceptive commodities are included on each list?*
- 17. Does the government limit itself to purchasing drugs or medical devices that are only on the NEDL? Is the registration process transparent to register new drugs or medical devices on the NEDL?
- 18. How are contraceptives that are not part of the country's NEDL or public sector Essential Health Package selected and approved for procurement?
- 19. Is equipment for long-term and permanent contraceptive methods included on the NEDL list (e.g., syringes, implant kits, and so forth)?

C. PRODUCT REGISTRATION

- 20. What are the national policies or regulations and the practices that govern the registration of drugs and medical supplies, including contraceptives?*
- 21. Which government agency is responsible for managing the product registration process?*
- 22. Is the drug or medical device registration process and practice the same for all commodities? Does the process differ for the following commodities?
 - Donated commodities
 - Government-procured commodities
 - Locally manufactured commodities
 - Commodities on the NEDL
 - Commodities not on the NEDL

How does it differ for each bulleted item?

- 23. What is the registration policy and practice for contraceptives? Are any contraceptive commodities treated uniquely in this process (e.g., condoms and intrauterine devices)?*
- 24. What is the registration status of the various contraceptives used in the country? Are they all registered? If not, why?
- 25. How long is the registration process?
- 26. How long is the product registration valid?
- 27. Is the registration process different for generic equivalents and for innovator products?
- 28. What is the cost to the supplier to register drugs and medical devices? Does it vary by innovator product versus generic product, product category, or national applicant versus international applicant?
- 29. Do any special provisions exist for drugs and medical devices already registered in the United States, the European Union, and Japan or by another "stringent" regulatory authority or for drugs and medical devices pre-qualified by the WHO? Is there reciprocal drug or medical device registration with other countries in the region?

D. QUANTIFICATION AND FORECASTING

- 30. Does a policy include guidance on forecasting for contraceptives?* If so, describe the policy and practice.
- 31. If a policy includes guidance on forecasting for contraceptives, which government agency is responsible for developing the policy and providing guidance on forecasting?
- 32. Which government agency or unit is responsible for developing forecasts for contraceptives?
- 33. How are forecasts for contraceptives prepared? Are they developed using logistics or demographic or service statistics data? How often are they prepared, finalized, and updated? List all methods and describe the entire process.
- 34. Are accurate data available for forecasting for each contraceptive method used?
- 35. Are forecasts prepared on a schedule consistent with budgeting and procurement cycles? Provide precise information on dates and so forth.
- 36. Have contraceptive commodity forecasts been accurate? If not, describe any recent issues.
- 37. How are contraceptive commodity forecasts used?

E. DEVELOPMENT OF PROCUREMENT PLANS

- 38. Do any policies provide guidance or requirements for developing procurement plans?* If so, describe the policy and practice.
- 39. Which agency or unit is responsible for developing procurement plans for contraceptives?*
- 40. What specific types of information are included in the contraceptive procurement plan?*
- 41. Have there been any problems developing procurement plans for contraceptives? If so, describe those problems.

F. BUDGETING AND FINANCIAL COMMITMENT

- 42. How often does procurement for government-financed contraceptives take place (e.g., quarterly or annually)? How does this timing coincide with government funding cycles in the country?
- 43. How is the agency responsible for procuring contraceptives notified that funds have been allocated and disbursed for the procurement?
- 44. Have any recent problems occurred in allocating and disbursing funds to support procurement activities? If so, describe those problems.

NOTE: For additional information on budgeting and funding commitments, see the following portion of this section about policies and practices as they relate to financing.

G. PREPARATION AND ISSUANCE OF TENDER

45. Using the sample table (table 4), describe the different types of methods allowed for procuring contraceptives and the criteria for using one method over another. Are other procurement mechanisms being used for other health commodities that could serve as a better option for contraceptives?

TABLE 4: PROCUREMENT METHODS AND CRITERIA

Procurement mechanism	Criteria for use
International competitive bidding	
Limited international competitive bidding	
National competitive bidding	
Direct purchasing	
Pooled procurement	
Shopping (indicate threshold)	
Other	

- 46. What are the financial thresholds for requiring international tendering versus national tendering?
- 47. Which procedures are available to the procurement staff that provide specific instructions on the proper methods for implementing tender and procurement processes? For example, is there a published set of desk instructions that procurement staff use?*
- 48. Describe a recent tender process for drugs, for drugs and medical supplies, or for both, including how practice may differ from policy:
 - Was a single tender issued for a large number of products with diverse requirements, or were tenders for fewer items grouped according to common product or drug classifications?
 - Were there any delays?
 - If so, what were causes of protests or delays?
- 49. Does a procedure or practice initiate emergency procurements in case of a stockout or other issue? If so, describe the procedure or practice.

H. QUALITY ASSURANCE IN THE TENDERING AND PROCURING PROCESS

Product quality assurance appears throughout the product life cycle, beginning with the manufacturer producing a product in accordance with required technical specifications and good manufacturing procedures and extending through procurement to delivery and proper storage and use by the patient. In the procurement process, quality assurance is addressed by including quality assurance requirements in product specifications and including the right to inspect and test products in the tender and contract requirements.

- 50. What are the procedures that provide guidance or requirements for developing product technical specifications for procurement?*
- 51. What agency or unit is responsible for preparing product technical specifications for procurement?
- 52. Do product technical specifications include or reference current international specification requirements? For example, do condom specifications reference a source such as the WHO's The Male Latex Condom: Specification and Guidelines for Condom Procurement 2003¹?
- 1. For additional information, see http://www.who.int/reproductivehealth/publications/family_planning/9241591277/en/.

- 53. Have there been, or are there currently, any problems in including quality assurance requirements in product specifications? If so, describe the problems.
- 54. If a product specification is lacking or is inadequate, what is the process or practice to include a full quality assurance specification in the tender?
- 55. Do any policies provide guidance or requirements for including in tender and contract documents the right of the purchaser to sample, inspect, and test products to make sure it complies with specifications and quality assurance requirements?
- 56. Which agency or unit is responsible for including sample, inspection, and testing rights in tender and contract documents?

I. TENDER EVALUATION AND SELECTION OF SUPPLIER

- 57. Do any policies provide guidance or requirements for evaluating tenders and selecting suppliers?* If so, describe the policy and practice.
- 58. How are criteria for evaluating tenders established?
- 59. Describe the tender evaluation process:
 - Who makes up the technical review committee to evaluate the tenders?
 - Who sits on the tender evaluation committee?
 - Is the whole committee involved in the evaluation and selection process?
 - Is the tender evaluation and award process made public?
- 60. Have supplier selection results and contract award decisions ever been protested by suppliers that failed to win the contract? If so, what are the more common reasons for protesting an award?
- 61. Have any tenders been voided or not awarded? If yes, why (e.g., nonresponsive bidders, poor prices, or noncompliant suppliers)?

J. ISSUANCE OF CONTRACT AND PAYMENT ARRANGEMENTS

- 62. Are contract awards issued within the period of the original tender validity date? If not, why?
- 63. When the government procures commodities, what is the accounts payable policy (e.g., how long to remit payments for received invoices)? What is the actual practice, or are there other issues with suppliers relating to late payment?

K. PRESHIPMENT INSPECTION

- 64. Do any policies provide guidance or requirements for determining which contraceptive commodities should be subject to preshipment inspection?*
- 65. Which agency or unit is responsible for determining whether preshipment inspection is conducted on contraceptive commodities?
- 66. If preshipment inspection is required, answer the following:
 - What specific quality testing occurs?
 - Who carries out the testing? Is testing contracted out to external laboratories?

- 67. If contraceptive commodities do not pass quality assurance inspection or testing, answer the following:
 - What actions are taken?
 - How long does this process take?
 - Are supplies quarantined until results are obtained?

L. CUSTOMS CLEARANCE, RECEIPT, AND INSPECTION

- 68. What are the policies and practices for customs clearance for contraceptives?*
- 69. Are any of the contraceptive commodities subject to duties, import tax, or other fees? If so, which fees? How much are the fees?
- 70. If no fees are applied, what policies exist to allow for exemptions? Describe the criteria and practice for tax exemption.
- 71. After contraceptive commodities clear customs, are they subject to inspection, to testing, or to both? If so, which items are inspected or tested? How long is the inspection or testing process?
- 72. What are the policies and practices when a contraceptive commodity fails pretesting and posttesting?

M. DECENTRALIZED PROCUREMENT SYSTEMS²

- 73. How do policies associated with a decentralized system affect health commodity procurement?
 - Are health commodities procured at a district or regional level, a central level, or a mixture of the two?
 - Are the procurement procedures the same across districts or regions?
- 74. Are regional or district levels allowed to procure, and do they have the ability to procure locally or internationally? If those levels are allowed by policy to procure locally, is the procurement done routinely and transparently and at the same cost as procuring from the central level? Have those processes resulted in stockouts at lower levels of the health system?
- 75. Are commercial sources available and accessible, and do they have the quantities and products required?
- 76. Is shopping³ allowed at the local level? If so, what is the ceiling?
- 77. Are local procurement prices generally lower or higher than those obtained from the national level?
- 78. Do the decentralized regions follow the same procuring and forecasting policies and practices as the central level?
- 79. Who at the lower level is responsible for coordinating procurement of drugs and health commodities?
- 80. Does a line item exist in the lower-level budgets for procuring drugs and health commodities? In other words, is the drug or health commodity budget ringfenced so that funds cannot be used for other expenditures?

^{2.} Decentralized systems are those in countries with decentralized administrative structures—provinces, districts, municipalities, or regions.

^{3.} Shopping generally allows local health centers to solicit three quotes, and then to choose the lowest price up to a certain limit. In some cases, shopping allows direct purchasing for limited value purchases.

N. OTHER ISSUES: CHALLENGES AND OPPORTUNITIES

- 81. What challenges does the procurement unit face as a result of the procurement policy and practices? Challenges may include obstacles such as lack of clear policies and procedures, insufficient number of staff members, lack of transparency, limited funding, and so forth.
 - What opportunities exist for overcoming the procurement-related challenges?
 - To what degree does the procurement unit have the capacity to address those challenges? Explain what additional capacity building is needed.
- 82. How often have disruptions or stockouts (or threat of disruptions) in contraceptive commodities occurred as a result of delays in government-financed procurement (at the central level)?
 - What were the causes of the stockouts?
 - What is being done to avoid them in the future?
 - What policies or practices are in place to help minimize stockouts?
- 83. Is there a policy or practice to initiate emergency procurements in case of a stockout? If so, what is the country's definition of and threshold for emergency procurements?
- 84. What opportunities exist for improving the procurement process for contraceptives? Would those improvements result in cost savings, reduced lead times, and so forth?

ASSESSING POLICIES AND PRACTICES RELATED TO FINANCING

Goal: Identify barriers to and options for improved financing policies for publicly procured contraceptives.

Background: This portion of section II focuses on the current financing polices, guidelines, and practices regarding public sector contraceptives. Fluctuations in the sources of funding, the timing of financial cycles and the complicated policies and procedures related to financing are issues that can undermine contraceptive security in many countries. The questions that follow are designed to gain a better understanding of the financing context and of the way it affects a country's ability to finance contraceptives.

Key areas: This section is organized according to the following key components of financing:

- Context
- Policies, procedures, and guidelines
- Decentralization

Points to keep in mind:

- Prior to examination of the policies, procedures, and practices related to the financing environment, it
 is important to identify relevant stakeholders. Although the MOF is an obvious source for this type of
 information, there may be others such as the Ministry of Planning and, in decentralized settings, the Ministry
 of Local Government. Working with those ministries to determine the most appropriate units to include in
 data collection can be challenging, but it is critical to understanding the situation. Donors (both those that
 contribute to a basket and those that are directly funding the family planning) are also key informants.
- In any discussion of financing, it is critical to use terminology consistently and to clarify terms for key informants. It is equally important to clarify the time period (fiscal year versus calendar year) followed by the country and currency denomination for data provided.

Expected outcome: The responses from this portion of section II should help accomplish the following:

- Understand both the existing and the changing finance environment and the way it affects contraceptive security.
- Understand how finance policies are implemented, and provide ideas of how to remove barriers that limit efficiency, effectiveness, and access.

Throughout the numbered items in this section, the questions that may be addressed as part of the desk-based review are indicated by an asterisk (see also "Methodology" in section I for the bulleted item titled "Desk review").

A. CONTEXT

- 1. Describe the national annual budget process in the public sector, considering policies and practices.
- 2. What is the overall budget for the health sector (including percentage of donor funds versus internally generated funds and so forth)?
 - a. What are the sources of funding?
 - b. What are the mechanisms (e.g., basket funds)?
- 3. Does the country use any of its own resources (i.e., internally generated funds, basket funding, direct budget support, or World Bank credit) for health sector financing? If so, provide the amount of financing using the sample table (table 5).

TABLE 5: GOVERNMENT FINANCING

Government funds	2006	2007	2008	2009	2010
Internally generated funds					
Basket funding					
Direct budget support					
World Bank credit					

- 4. How does the government incorporate those commitments of donors who do not put their money directly into any basket mechanism in the budget-planning process?
- 5. Does a government-sanctioned or legally binding national strategic plan (e.g., Medium Term Expenditure Framework) exist that ensures an adequate or minimum amount of funding for contraceptives?*

 Describe all national strategies that include financing for contraceptives.
- 6. Does a poverty reduction strategic plan (PRSP) exist that specifically addresses family planning or reproductive health? Are indicators, outcomes, and funding commitments indicated in the strategy?**
- 7. Are any conditions attached to contraceptive commodity financing? That is, do funds have to be spent on specific contraceptives or by a specific time or is there flexibility?
 - Do any operational policies describe those conditions? If so, what are the actual practices and are the operational policies followed? If not, what are the exceptions and why? What are other issues?
- 8. Are any changes anticipated in future funding trends—shift to direct budget support, changes in developing partner allocations or in priorities, or use of different funding mechanisms—that will affect the ability to procure all required contraceptives?
- 9. Is enough funding available to procure the needed amounts of contraceptives for (a) the next year or (b) the next three years? If not, describe the funding gap and possible reasons for the gap.
- 10. What are the constraints or barriers to fully financing contraceptive commodities?
- 11. Is financing adequate to procure other health commodity requirements in the country for (a) the next year or (b) the next three years? If not, describe the funding gap and possible reasons for the gap.
- 12. What information is used to develop a budgetary request for procuring contraceptives (e.g., national forecasts and estimates from previous years)?
- 13. What type of regular planning does the government do to discuss available financing for meeting contraceptive requirements?
- 14. What are the sources of financing for contraceptives? Using the sample table (table 6), fill in funding committed according to source for past procurement (for trend analysis) and future commitments. The years and sources should be amended as needed. This section can be partially filled out as part of the policy audit.

TABLE 6: HISTORICAL AND FUTURE FINANCING FOR CONTRACEPTIVE METHODS AND COMMODITIES

Commodity	2007	2008	2009	2010	2011
By method	I	1	1	1	ı
Government ^a					
U.N. Population Fund					
U.S. Agency for International Development					
U.K. Department for International Development					
Kreditanstalt für Wiederaufbau					
International Planned Parenthood Federation					
Population Services International or DKT International					
Other					

Note:

- a. "Government" can refer to national, state, provincial, or other local authority.
- 15. Does the government have a dedicated budget line for the procurement of contraceptives or contraceptive commodities?
- 16. Map out the key steps for government financing of contraceptives for the public sector, including budget preparation and disbursement of funds. Use the sample process map (figure 3) as a guide:
 - a. Identify the national laws and policies.
 - b. Identify the principal organization responsible for implementing each key step in the process.
- 17. Describe budget cycles for major donors.
- 18. Does a sector-wide approach (SWAp) exist for health?
- 19. If a SWAp exists for health, are family planning or reproductive health products or both explicitly included in the SWAp agreement? Describe how family planning is addressed and how it came to be included. Does the SWAp have a basket-funding mechanism (i.e., pooled funds)?
- 20. What happens if the central procurement agency has funds remaining at the end of the fiscal year? That is, are those funds transferred back to the country's treasury?

B. POLICIES, PRACTICES, AND GUIDELINES

- 21. What finance and budget policies are in place to channel government funds for procuring contraceptives (e.g., budget line item, annual budget negotiation process, government order, or law)?* What are the practices for allocating, disbursing, and expending public funds for procuring contraceptive commodities at the national level?
 - a. What polices or guidelines exist to direct those funds?
 - b. Who makes the decision on how much should be obligated? How is the decision made?
 - c. What percentage of this amount is actually disbursed, and how frequently is it disbursed? Who (which agency) receives the disbursement?
 - d. Describe how funds flow from disbursement to procurement.
 - e. How does this disbursement schedule affect procurement efficiencies?
- 22. What are the perceptions of specific groups regarding the effectiveness and efficiency of the finance-related policies (e.g., contraceptive commodity security committee, ministries, donors, multilaterals, parliamentary groups, regulatory groups, private sector and NGOs, health care providers, and civil society)?
- 23. What opportunities exist for overcoming the finance-related challenges?
- 24. What decision-making power exists for the program unit to implement finance-related policies?
- 25. How often does the family planning or reproductive health program unit involve others to address finance policy challenges?
- 26. On the basis of the above response, whom are they involving?
- 27. What additional actions are needed to improve the financing policies and practices, including improvements in efficiency and effectiveness of financial resources?
- 28. Who is involved in implementing policies as they relate to financing contraceptives? Describe the role and level of their involvement in policy implementation.

C. DECENTRALIZED SYSTEMS⁴

- 29. In a decentralized system, do the districts or regions have control over the budget for procuring contraceptives?
- 30. How is the budget for contraceptives determined at the decentralized level?
- 31. Does a budget line item exist for contraceptives in the regional or district health budget?
- 32. Does the region, district, or facility generate funds that can be used for the purchase of contraceptives? If so, describe that practice.
- 33. If any financing for contraceptives comes from the central level, what coordination takes place between the regional and central levels to decide the final amount for contraceptives?
- 34. If a funding request is made to the central level, does it arrive as scheduled and in the amount requested?
- 4. Decentralized systems are those in countries with a decentralized administrative structure (i.e., provinces, districts, municipalities, or regions).

- 35. Is any unspent funding slated for health commodities or contraceptive commodities required to be returned to the central level at the end of the budget cycle?
- 36. Who at the regional or district level makes the decision whether to purchase contraceptives?
- 37. Do policies exist to guide the responsible individuals in making those determinations?
- 38. How do regional or district finance policies treat donated drugs as compared to purchased or procured drugs?

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APPENDIX A

GLOSSARY

Basket funding Also known as pooled funding, basket funding is a mechanism whereby

financing entities place their funds into a single account and withdraw funds to meet specified objectives. In the international development field, this mechanism is particularly common within sector-wide approaches (SWAps).

Contraceptive security Contraceptive security exists when every person can choose, obtain, and use

high-quality contraceptives and condoms whenever needed.

Coordinated informed A CIB is a pooled procurement option whereby member countries

buying (CIB) undertake joint marketing research, share supplier performance

information, and monitor process. Countries procure individually.

Direct budget support is an aid-financing modality in which the donor

provides the financing directly to a recipient country government through

its national treasury.

Direct purchasing occurs when a purchaser contracts for goods directly

with a manufacturer or its representative.

the specified national procurement process. Countries will have varying

definitions of and thresholds for emergency procurements.

Financing Financing is the processes or mechanisms that provide resources for a

program, service, or purchase. In the context of this guide, it includes any source of resources—including donor funding—for a country's contraceptive program. Financing includes resources for the purchase or procurement of contraceptives. In a decentralized setting, financing of contraceptives may come from a district or province, depending on the country context.

come from a district or province, depending on the country context.

Government funding Government funding can include internally generated funding as well as basket funding provided by donors, World Bank credits, and direct

budget support.

International competitive

bidding (ICB)

ICB is a method for procuring goods and services that requires notification to the international community. Bidders from eligible countries, as defined by the contracting agency or country, are given an equal opportunity to bid.

Limited international

competitive bidding (LICB)

LICB is essentially the same as international competitive bidding but is done by direct invitation without open advertisement. This method of bidding is traditionally used when the contract values are small, when the number of suppliers is limited, or when special circumstances exist.

Obligated Obligated funding is funding that has been set aside for spending but

has not yet been released or allocated.

Operational policies Operational policies are the rules, regulations, codes, guidelines, plans,

budgets, procedures, and administrative norms that governments use to

translate national laws and policies into programs and services.

Operational policy barriers
Operational policy barriers are the policies that may pose obstacles or

challenges to service delivery because of the lack of policy guidance, the misguided design of the policy, or the misguided implementation

of the policy.

Pooled procurement Pooled procurement is an approach to ensure a consistent and sustainable

supply of essential medicines. It involves purchasing done by one procurement office on behalf of a group of facilities, health systems, or countries. In return, members agree to purchase certain drugs exclusively through this mechanism. Successful pooled procurement schemes can lead to reductions in unit prices for medicines, to improvements in procurement and quality assurance systems, and to increased capacity levels in individual

countries.

Practices Practices are those systems or procedures that implement a particular

process. In the context of this assessment guide, practices refer to those procedures and behaviors that implement a policy or process for procuring and financing contraceptives. Sometimes, practices serve as operational policies in the absence of any formal guidance. Ideally, governments formalize good practices with operational policies such as guidelines or

regulations—instances in which policy follows practice.

Process map A process map is a tool for conducting a work flow analysis and

improvement. It is a diagram that describes the chronological sequence of work steps used to achieve a particular desired outcome or result. It is

sometimes called a flow chart.

Procurement Procurement is the identification of suitable sources of supply and the

acquisition—as economically as possible and within established quality

standards—of commodities according to a procurement plan.

Quality assurance and control Quality assurance and control is a planned and systematic approach to

monitoring, assessing, and improving the quality of health services on a

continuous basis within the existing resources.

Sector-wide approach (SWAp) A SWAp is a financing and management approach by government and

development partners to increase government ownership and coordination for a sector such as health. SWAps can be financed through pooled funding, called baskets, to support and implement an agreed upon framework of

priorities and objectives.

Shopping Shopping occurs when local health centers solicit three quotes and choose

the lowest price up to a certain limit. In some cases, shopping allows direct

purchasing for limited value products.

APPENDIX B

SAMPLE SCOPE OF WORK

SCOPE OF WORK EXAMINING THE POLICIES, GUIDELINES, AND PRACTICES THAT AFFECT PROCURING AND FINANCING CONTRACEPTIVES IN [COUNTRY] [DATES]

INTRODUCTION AND RATIONALE

Contraceptive security exists when every person can choose, obtain, and use high-quality contraceptives and condoms whenever needed. Achieving contraceptive security requires efficient contraceptive procurement and financing mechanisms, as well as procedures that are designed to secure low prices and to prevent product shortages and stockouts.

Functioning policies related to procuring and financing contraceptives provide an enabling environment and, when implemented effectively and efficiently, serve as the foundation for the effectiveness of those systems. Analyzing the policy environment related to procuring and financing contraceptives can help to determine the root causes of a health system's poor performance and to identify opportunities for improvement.

This activity is intended to assist national governments, donors, and other key stakeholders in improving the policy environment and practices for contraceptive security.

Operational policies are the formal or informal rules, regulations, codes, guidelines, plans, budgets, procedures, and administrative norms that governments use to translate national laws and policies into programs and services. *Practices* are defined as the systems or procedures used to implement a particular process. Sometimes, practices serve as operational policies in the absence of any formal guidance.

Operational policy barriers are the operational policies or practices that may pose obstacles or challenges to commodity security as a result of misguided design or misguided implementation. A standard methodology has been developed for assessing where policy bottlenecks exist in financing and procuring family-planning products.

[COUNTRY] ACTIVITY DESCRIPTION

[Insert language regarding why this activity is appropriate for the country]

METHODOLOGY

The methodology for this activity in [country] includes two phases: (a) understanding of the policy and stakeholder landscape, and (b) validation of the landscape and identification of critical operational policy barriers that negatively affect contraceptive security.

- 1. Policy and stakeholder landscape
 - Conduct a desk-based review of country documents to ensure a basic understanding of the country context and to ensure support of the identified needs and existing strategies by the study.
 - Engage key stakeholders to determine interest in and appropriate timing of the activity.

- Adapt the process and approach to the [country] context.
- Conduct a policy audit to inventory all policies, regulations, and guidelines that may affect the financing and procuring of health commodities, particularly contraceptives.
- Map out the steps involved in procuring and financing contraceptives, and then identify the stakeholders who develop, implement, oversee, and monitor or are affected by the pertinent policies and regulations.
- 2. Validation and identification of critical barriers
 - Conduct key informant interviews, and continue review of documents to accomplish the following:
 - Clarify the existence of and identify barriers or gaps in relevant policies and practices.
 - Compare policies as designed and intended to be implemented against practice and perception of policies.
 - Identify issues and generate recommendations to improve the policy environment for financing and procuring contraceptives in [country].

The assessment will generate concrete findings and recommendations that can be used to help support [country] to improve its contraceptive security situation. It will also be used to refine the overall approach and methodology and to determine its effectiveness in helping a country uncover such issues.

REQUIRED SKILL SET FOR ASSESSMENT

The necessary skills are as follows:

- Experience and background with government financing and procurement policies, laws, and practices
- Familiarity with developing partner aid and funding mechanisms
- Familiarity with family planning and reproductive health issues
- Familiarity with procurement practices for reproductive health commodities
- Competency in research and analysis

TEAM MEMBERS

[List team members and their affiliation.]

APPENDIX C

SUGGESTED ISSUES AND POLICIES FOR DESK-BASED POLICY AUDIT

- Legislative and policy framework
 - Procurement act (i.e., the Public Procurement and Disposal of Public Assets Act)
 - Are the main procedures for the key procurement methods, such as request for quotations and tendering, outlined in the act?
 - National medicine policies, which aim to ensure that good-quality, safe and efficacious, and affordable medicines are available
 - "Buy local" policy that affect importation or local manufacture of contraceptive products
 - Having policies on taxes and duties on drugs and devices, as well as taxes and duties on raw materials for the manufacture of drugs and devices
 - Granting tax breaks, lowering registration fees and tariffs, and reducing duties on raw materials to companies producing locally
 - Encouraging public procurement systems to purchase locally when quality can be ensured (e.g., preferential treatment of 15 percent price reduction for local manufacturers)
- Guidelines and regulations
 - International reference guidelines and standard operating procedures
 - National Essential Drug Lists and National Essential Medicine Lists
 - Standard Treatment Guidelines
 - Registration guidelines and requirements on drugs, medicines, and commodities
 - Procurement procedures
 - Stringent Regulatory Authority (SRA) or World Health Organization (WHO) prequalification requirements
 - Third-party procurement guidelines
- Institutions (What are the mandates and functions of each institution related to the procurement process and activities? Who has final say for procurement?)

Institution	Mandate
Food and drug authority	
Nondrug authority (nonmedical authority)	
Procurement and disposal of assets or oversight authority	
Public procurement and regulatory agencies	
Central Medical Stores	
Ministry of Health, reproductive health unit	
Ministry of Finance	
Revenue authority	
Central Tender Board	
Pharmacy Board	
Registration units	

Procurement-related issues

- Preferred procurement methods: Open or competitive bidding
- International obligation: International obligation prevails or national legislation prevails
- Prequalification of suppliers or bidder: Acceptable or not applicable
- Third-party procurement: Acceptable or not applicable
- Lack of coordination or fragmented procurement
- Financing-related issues
 - Method of payment
 - letter of credit
 - bank transfer
 - checks or bank drafts
 - Access to and use of convertible currency for international procurement
 - Insufficient government funding or irregular release or both
- Pricing
 - National medical policies: Some components address pricing issues.
 - Public sector procurement prices: Some prices may be found to be below the international reference price.

• Financing sources

- Some financing sources may restrict procurement to an agreed list of commodities.
- Some financing agents may restrict use of funds to procurement from named sources or countries.
- Some financing agents may restrict procurement to products approved by named product quality standard agencies (e.g., European Medicines Agency (EMEA) and U.S. Food and Drug Administration (FDA).

Product Types

 Some countries may restrict or prohibit procurement of certain contraceptive drugs or dosage forms (e.g., injectable or barrier contraceptives).

Context

- Inadequate implementation of existing policies, laws and acts, and regulations
- No national policies and regulations
- Preferential treatment for local or national bidders: Acceptable (not being implemented) or acceptable (being implemented)
- Bureaucracy and heavy administrative procedures
- Poor availability in the public sector
- Lack of capacity
- Interpretation of policy (typically lack of understanding)

APPENDIX D

ADDITIONAL RESOURCES

PROCUREMENT-RELATED INFORMATION AND RESOURCES

- The Global Fund. 2003. "Procurement and Supply Management (PSM) Assessment Tool." http://www.who.int/hdp/publications/13ki6.pdf.
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- Program for Appropriate Technology in Health (PATH). 2009. "Procurement Capacity Toolkit: Tools and Resources for Procurement of Reproductive Health Supplies. Version 2." November. http://www.path.org/publications/details.php?i=1652.
- United States Pharmacopeial Convention. 2007. Ensuring the Quality of Medicines in Resource-Limited Countries:

 An Operational Guide. Rockville, MD: United States Pharmacopeial Convention. http://www.usp.org/pdf/EN/dqi/ensuringQualityOperationalGuide.pdf.
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- ———. 2002. Practical Guidelines on Pharmaceutical Procurement for Countries with Small Procurement Agencies. Manila: WHO Regional Office for the Western Pacific. http://www.wpro.who.int/NR/rdonlyres/7D1B522D-DEB1-48CB-88A7-68DEB599CCE1/0/PharmaProcurementGuide.pdf.

FINANCING-RELATED INFORMATION AND RESOURCES

- Ortiz, Christine, Nadia Olson, Mark McEuen, and Paul Dowling. 2008. "Primer: Ensuring Reproductive Health Commodity Security within a Sector Wide Approach." USAID | DELIVER PROJECT, Task Order 1, Arlington, VA. http://pdf.usaid.gov/pdf_docs/PNADN673.pdf.
- USAID | DELIVER PROJECT. 2008. "Policy Brief: Using National Resources to Finance Contraceptive Procurement." USAID | DELIVER PROJECT, Task Order 1, Arlington VA. http://deliver.jsi.com/dlvr_content/resources/allpubs/logisticsbriefs/Using_National_Resources_Final_tagged.pdf.

OTHER RELATED INFORMATION AND RESOURCES

- Global Fund Procurement and Supply Management (PSM) Assessment Tool. Accessed 2010. http://www.who.int/hdp/publications/13ki6.pdf.
- International Drug Price Indicator Guide. Accessed 2010. http://erc.msh.org/mainpage.cfm?file=1.0.htm&&module=DMP&language=English.
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For more information, please visit http://www.healthpolicyinitiative.com and deliver.jsi.com.

USAID | Health Policy Initiative, Task Order I

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