PEPFAR

U.S. President's Emergency Plan for AIDS Relief

CHAPTER THREE.

COMMODITIES, PROCUREMENT & SUPPLY CHAIN CONSIDERATIONS

PEPFAR'S BEST PRACTICES FOR VOLUNTARY MEDICAL MALE CIRCUMCISION SITE OPERATIONS

A Service Guide for Site Operations

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CHAPTER 3.
Commodities, Procurement & Supply Chain Considerations

CHAPTER GOALS

To ensure site-level staff are able to do the following:

- Procure the necessary commodities to provide VMMC services that meet PEPFAR standards within a prescribed time frame.
- Understand the discrete steps in the procurement process and the resources to assist site managers with completing these steps.
- Remain aware of steps in the procurement process that are particularly prone to delays due to the reliance on external actors (manufacturers, customs, and importation regulators) so that stock-outs are minimized.

WHAT USERS NEED TO KNOW

Without the appropriate commodities and equipment, VMMC service delivery cannot take place. The required commodities and equipment include pharmaceuticals, surgical instruments, and medical and waste management supplies, to name a few. Site managers must account for and resolve common procurement-related challenges, given limited options for local sourcing of commodities and the complexities of international sourcing. [See **PEPFAR Male Circumcision Partners' Meeting: Commodities and Improved Coordination of Male Circumcision for HIV Prevention**]. Because human resource constraints limit staff availability to manage the supply chain for commodities, tools are provided that outline the technical specifications for requisite commodities agreed by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) Voluntary Medical Male Circumcision Technical Working Group (VMMC TWG). [See **SCMS E-catalog (including male circumcision kit options)**]. These tools also enable consumption forecasting to ensure adequate stock on hand. [See **Quantification, Forecasting, and Monitoring Basic Tool for VMMC**]. Site managers, working with implementing partner program managers and procurement officers, are key personnel who prevent and address stockouts, determine how and when to order supplies, and manage the tracking and budgeting of commodities. [See **Costing Tool for Public Hospitals—Male Circumcision Model**]. There are 10 steps in the procurement process.

Tools are available specifically to assist with step 2 above. [See **SCMS Intro Letter 2012** and **PFSCM Client Toolkit**]. Finally, to ensure safety and quality, PEPFAR-supported services should procure commodities that meet U.S. and national government regulatory requirements or can be approved via appropriate agency guidelines such as USAID's Automated Directives System (ADS) 312. [See **ADS 312 USAID Pharmaceutical Approval Process**].

10 STEPS IN THE PROCUREMENT PROCESS:

1. Definition of specifications
2. Creation of price request and price quote
3. Approval of price quote
4. Purchase order/sales order creation
5. Allowance for vendor lead time (manufacturing time)
6. Shipping document creation
7. Customs pre-clearance procedures
8. Delivery to port of entry
9. Customs clearance
10. Local delivery to warehouse.

It is important to conduct a forecasting and supply planning exercise with all partners at the program level. This exercise should include multiple demand scenarios and should occur at least annually with quarterly updates. [See **Quantification, Forecasting, and Monitoring Basic Tool for VMMC**]. Generally, the forecasting and supply planning exercise is taken on by the chief pharmacist or nurse in collaboration with site managers and procurement officers. Chief pharmacists, nurses, site managers, and procurement officers are also the key personnel who prevent and address stock-outs, determine how and when to order supplies, and manage the tracking and budgeting of commodities. [See **Costing Tool for Public Hospitals—Male Circumcision Model**]. In addition to the forecast scenarios, the in-country teams should review the supply plans quarterly, given that demand may be seasonal and may change rapidly due to the voluntary nature of the program. PEPFAR works with external partners who are cautiously approved through a competitive bidding process to provide a reliable, cost-effective, and secure supply of products for HIV and AIDS programs in PEPFAR-supported countries. VMMC programs may choose to procure their commodities and supplies using such approved partners.

FREQUENTLY REFERENCED INFORMATION

Commodities information is frequently modified due to updates in kit content specifications and item codes, among other things. Instead of including detailed information subject to change, the following website should be checked for the most current information:

http://scms.pfscm.org/scms/ecatalog/mc

A section of the webpage is included as a worksheet on **page 38** to show readers the information provided on the website.

FOR ADDITIONAL INFORMATION

Conducting an efficient, high-quality VMMC program largely depends on the commodities available. Unfortunately, because many of the regions where VMMC programs are needed have limited financial and human resources, it is difficult to manage the procurement of VMMC commodities. Required commodities include a wide variety of items such as pharmaceuticals, medical supplies, waste management commodities, prefabricated surgical units, to mention a few (Edgil, Stankard, Forsythe, et al. 2011). These commodities may require substantial lead times from order placement to delivery and installation at the VMMC service provision site. For many countries, medical suppliers have limited warehouse capacities and difficulties in sourcing items internationally, which makes the scale-up of commodities and supplies challenging. [See **PEPFAR Male Circumcision Partners' Meeting: Commodities and Improved Coordination of Male Circumcision for HIV Prevention**].

PROCUREMENT

Whether products are sourced locally or internationally, strong quality assessment (QA) processes must be implemented when vetting suppliers to ensure that goods and pharmaceuticals procured meet U.S. Government regulatory requirements or, if procured through USAID, can be approved via USAID's **ADS 312 USAID Pharmaceutical Approval Process**. Procurement should be transparent and allow for sufficient lead time. The procurement process may take as little as six weeks or as long as a year, depending on the product, manufacturer stock levels, and lead times.

STEPS OF THE PROCUREMENT PROCESS

Site Level

- **Definition of Specifications:** Project managers and site managers must be knowledgeable about the appropriate items needed for their program and must be able to procure the correct commodities. The PEPFAR VMMC TWG has developed the specifications of commodities to be used in PEPFAR-funded VMMC programs. PEPFAR partners should procure commodities in line with those specifications. The specifications can be found in the SCMS E-catalog. [See **SCMS E-catalog (including male circumcision kit options)**]. Updated references will be provided should new procurement agencies determine that alterations in commodities and supply chain processes are necessary.

Above Site Level

- **Creation of price request and price quotation:** This item refers to steps that are needed to identify the products and quantities requested, as well as the terms of sale and the type and location for the transfer of goods. [See **PFSCM Client Toolkit and SCMS Intro Letter 2012**]. Although in principle this should be a relatively short procedure, it can be lengthened by a lack of clarity regarding the parties responsible for the customs clearance and storage processes. This procedure can also be lengthy for certain products in cases of global shortages or to comply with mandatory bidding processes based on federal acquisition regulations. To minimize delays, VMMC program managers should complete the **client and recipient information**, as well as the **shipping instructions forms**. In addition to accurate information, clear specifications of the product required (with product codes), quantities needed, and requested time of delivery should be provided.

- **Approval of price quote:** The acceptance of the price quote requires the signature of a designated U.S. Government representative and is normally resolved quickly. Several steps can be taken to ensure the timely approval of a price quote: clearly defining the specifications, determining correct initial assessments of program commodity needs and expected client demand, and assuring the complete understanding of the VMMC program implementation plan and its needs for commodities. Communicating all the site's needs up front will prevent having to repeat the steps above, thus reducing or preventing delays.

- **Purchase order/sales order creation:** After the approval of the quote, the site manager or procurement officer can work with the project manager to develop a purchase order. This process should take anywhere from a few days to a few weeks, though delays can occur due to product unavailability.

- **Vendor lead time (manufacturing time):** This item, which specifies the time needed by the vendor to secure the commodity requested, varies among product lines. Vendor lead time is minimal when products are in stock, or it can take several months if a product must be custom designed or manufactured to order. When developing the purchase order/sales order, it is important to confirm that the items are in stock so that time lag in delivery can be kept to a minimum.

- **Shipping documents creation:** This process creates the shipping and importation documents that are needed to move the cargo to its destination. The provision of accurate partner and destination information is critical in this step. This procedure can be problematic for newly launched VMMC programs that need to order a product before a supply chain and logistics plan has been developed. However, shipments that move forward without accurate information can be delayed in the customs process for months.

- **Customs preclearance procedures:** This item refers to the steps necessary to secure permits or waivers for importing health-related commodities. These procedures change by country, and lead times range from very quick to extremely lengthy. Country regulations should be verified before placing orders to prevent delays and also to minimize the approval procedure.

- **Delivery to port of entry:** Time required to complete this process can vary depending on the mode of transportation selected, the distance between supplier and client, and the availability of services in the countries where the producer and the receiver are located. For certain items and situations (large, bulky, items with a long shelf life, such as VMMC kits with a 24–30 month shelf life), a slower method of transportation will be selected (e.g., ocean, truck), and for others a faster alternative should be used (e.g., air).

- **Customs clearance:** The time required to complete this procedure, which takes place at the port of entry, should be short if all preclearance requirements have been fulfilled. In cases where shipping occurs before verification of regulations, this procedure can take a very long time—or could even lead to merchandise detention. In most African countries, customs clearance will take a couple of days, but this can vary from country to country.

- **Local delivery to warehouse:** Once the cargo has been cleared through customs, it will be transported to the storage warehouse. The time required to complete this step can depend on distance, mode of transportation, and destination country, among other factors. In addition, the need to distribute stock to multiple warehouses in one country can further delay this process.

Project managers and site managers should work closely with their procurement service agent (e.g., PrionTex, IDA, or Missionpharma) to ensure that lead times associated with each step are expedited as much as possible.

LOGISTICS

The forecasting, supply planning, procurement, and logistics planning for VMMC program commodity needs are critical for the timely delivery and distribution of commodities to support VMMC service delivery [See **Quantification, Forecasting, and Monitoring Basic Tool for VMMC**]. These needs are identical at the program level and at the individual site levels. If previous consumption and demand data on which to base a prediction are not available, it can be a challenge to quantify commodity needs accurately prior to the launch of a VMMC program. For this purpose, a forecasting and supply planning exercise with multiple demand scenarios should be conducted with all partners at the program level at least six months before services begin.

Decisions should be made regarding the parties responsible for ordering, procuring, importing, and storing commodities, as well as for distributing them to local sites and monitoring commodity usage and stock on hand. The volume of goods needed to perform thousands of VMMCs can overwhelm on-site storage capacity. Therefore, it is critical to identify a central storage facility and to design a distribution system that can meet the consumption needs of each site.

It is also important to note some additional supply chain considerations for temporary sites. For example, a fixed site that will serve as the source of commodities for temporary sites should be selected. Also, minimal storage capabilities, along with a closely monitored consumption system, should be in place at temporary sites.

VMMC KITS

Key to commodity procurement are decisions about whether to use a single, completely disposable kit that includes all the surgical instruments and consumables required to perform one VMMC procedure or to use a combination kit that comprises a pack of single-use supplies (gauze, needles, scalpel blade, gloves, etc.) and a set of reusable surgical instruments that can be sterilized and reused [See **SCMS E-catalog (including male circumcision kit options)**]. It is important to note that the PEPFAR VMMC TWG has developed standards for seven VMMC kits. These kits have been standardized to allow economies of scale, accepted quality standards, and the possibility of stocking kits in regional distribution centers to reduce lead time. The seven kits are:

- *Single-use VMMC kit for forceps-guided procedure*
- *Single-use additional pack of metal instruments for dorsal slit/sleeve resection procedure (to be used with the single use VMMC kit for forceps-guided procedure)*
- *Reusable set of metal instruments for forceps-guided procedure*
- *Reusable set of metal instruments for dorsal slit/sleeve resection procedure*
- *Essential consumable pack (to be used with reusable set of metal instruments for any surgical method)*
- *Single-use PrePex device kit*
- *Single-use VMMC kit for all surgical methods.*

See **Table 3.1** for a list of advantages and disadvantages of disposable versus reusable VMMC kits. Although the surgical kit is standardized, injectable anesthetics and other pharmaceuticals have not been included intentionally because these are medicines that often require entirely separate procedures for procuring, shipping, and importing into each PEPFAR country.

Table 3.1. Advantages and Disadvantages of Single-Use vs. Reusable VMMC Kits

VMMC KITS WITH SINGLE-USE INSTRUMENTS	VMMC KITS WITH REUSABLE INSTRUMENTS
ADVANTAGES	
– Ensure high-quality, sterile content in both nonhospital and hospital settings – Logistically and operationally easier, especially in mobile outreach services – Reduce initial startup program costs – Eliminate autoclave maintenance, personnel, training, and other costs – Consumables and single-use instruments can be combined into one kit – Can be bundled to ease ordering and managing of supplies – Increase service delivery efficiency.	– Ensure high-quality, sterile content in both nonhospital and hospital settings – Well-maintained reusable instruments may be easier to use than single-use stainless steel instruments – Build health system capacity and infrastructure – Employ local personnel – Create less waste and thus less need for waste management procedures – Require fewer long-term resources to procure additional instruments.
DISADVANTAGES	
– Create substantial amounts of waste, including stainless steel instruments that require smelting or burying, thus raising environmental concerns – Limit the flexibility of clinicians to use their preferred equipment and surgical method – Are prone to losing some contents to theft, which could compromise the sterility of the remaining contents.	– Require additional staff time for cleaning, sterilizing, and packaging instruments and for monitoring procedures – Require autoclave availability and regular maintenance for sterilization – Require water and power supply at site of autoclaving – May require additional time for procurement because kits are secured from multiple sources – Initial cost may be high.

In addition to the kits, additional supplies, as well as infection prevention procedures, will be needed for each VMMC. Operating theaters will need to be furnished, and emergency medical situations will need to be managed. Commodities to address these program aspects are outlined in the SCMS e-catalog (including male circumcision kit options) and are divided into four modules:

- Module 1: Additional Essential Products for VMMC Kits
- Module 2: Infection Prevention Supplies
- Module 3: Operating Theater Equipment
- Module 4: Emergency Medical Management Supplies

TOOLS, INSTRUMENTS, & GUIDANCE DOCUMENTS (9)

1. PEPFAR Male Circumcision Partners' Meeting: Commodities and Improved Coordination of Male Circumcision for HIV Prevention
2. SCMS E-catalog (including male circumcision kit options)
3. Quantification, Forecasting, and Monitoring Basic Tool for VMMC
4. Costing Tool for Public Hospitals—Male Circumcision Model
5. SCMS Intro Letter 2012
6. PFSCM Client Toolkit
7. Automated Directives System (ADS) 312 USAID Pharmaceutical Approval Process
8. **Client and Recipient Information Form**
9. **Shipping Instructions Form**

REFERENCE

Edgil, Dianna, Petra Stankard, Steven Forsythe, et al. 2011. "Voluntary Medical Male Circumcision: Logistics, Commodities, and Waste Management Requirements for Scale-up of Services." *PLOS Medicine* 8(11):e1001128. doi:10.1371/journal.pmed.1001128.

ABBREVIATIONS

ADS	**Automated Directives System [ADS]**
HCWM	**health care waste management**
PEPFAR	**U.S. President's Emergency Plan for AIDS Relief**
PFSCM	**Partnership for Supply Chain Management**
QA	**quality assessment**
SCMS	**Supply Chain Management System**
USAID	**United States Agency for International Development**
VMMC TWG	**Voluntary Medical Male Circumcision Technical Working Group**

EXCERPT FROM SCMS/PEPFAR E-CATALOG

VOLUNTARY MEDICAL MALE CIRCUMCISION

Ordering VMMC products from SCMS:

- Access list of all core VMMC products.
- Download the PDF version of the core VMMC products list.
- **Kits are custom-designed** specifically for this program. Items from any kit option or the supplementary modules cannot be removed, supplemented or substituted.
- A **standard list of pharmaceuticals** is also available for purchase separately, as such products fall under a different set of packaging, shipping and regulatory requirements.

The PEPFAR VMMC TWG recommends the following VMMC kits and device:

- *Forceps-Guided Procedure Kit* (Reusable)
- *Forceps-Guided Procedure Kit* (Single Use)
- *Dorsal Slit or Sleeve Resection Procedure Kit* (Reusable)
- *Additional Instruments Kit* (Dorsal Slit or Sleeve Resection Kit - Single Use)
- *All Surgical Methods Kit* (Dorsal Slit or Forceps Guided Kit - Single Use)
- *Essential Consumables for MC Kit* (Single Use)
- *PrePex Sutureless Clamp Device* (Non-Surgical)
- *PrePex Removal Device Kit* (Single Use)

Additional Products for VMMC Programs

The PEPFAR VMMC TWG has also recognized the need for additional commodities to support VMMC programs.

- Essential Products for the Disposable VMMC Kit
- Module 1. Infection Control and Prevention
- Module 2. Equipment for VMMC Kit
- Module 3. VMMC Emergency Supplies

Order Lead Time for Kits

The current lead time for any VMMC kit is about three months for manufacturing, plus four weeks for air shipment or 8 to 10 weeks for ocean shipment. These lead times are dictated by the manufacturer and are subject to change. SCMS will advise clients with a best estimate for delivery date shortly after an order is entered into the system.

Voluntary Medical Male Circumcision Health Care Waste Management Toolkit

Due to the scale of VMMC programs, it will be essential to include medical waste management measures. It is the responsibility of each country to plan for and implement waste management protocols. SCMS has developed a **Voluntary Medical Male Circumcision Health Care Waste Management Toolkit** to provide guidance on implementing health care waste management (HCWM) best practices for VMMC campaigns.

Basic VMMC Tool for VMMC and Rapid Test Kit (RTK) Estimations

The basic **VMMC tool** is a macro-based Excel application one can download to create basic VMMC and RTK estimations. The tool includes monitoring applications for target vs. actual number of procedures, consumption of commodities and end-of-month inventory of supplies. In addition, the tool includes automatic graphs for the monthly procedures comparison and the consumption and inventory of disposable VMMC kits.

Please Note: This tool is not supposed to replace forecasting and supply planning exercises in country.

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