

4. Procurement of Commodities

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* 3–4 months additional lead time for temporary sites

Useful Tools	<p>6 SCMS Intro Letter 2012</p> <p>7 PFSCM Client Toolkit</p> <p>8 Automated Directives System (ADS) 312 USAID Pharmaceutical Approval Process</p> <p>9 Quantification, Forecasting, and Monitoring Basic Tool for VMMC</p> <p>10 Male Circumcision Model—Costing Tool for Public Hospitals</p>
Useful International Guidance Documents	<p>3 Supply Chain Management System (SCMS) E-catalog including all Male Circumcision Kit Options</p> <p>5 PEPFAR Male Circumcision Partners’ Meeting: Commodities and Improved Coordination of Male Circumcision for HIV Prevention</p>

Objective(s): To procure the necessary commodities to allow the provision of VMMC services that meet PEPFAR standards within a prescribed time frame

Description: Conducting an efficient and high-quality VMMC program is largely dependent on the commodities available. Unfortunately, many of the regions where VMMC programs are needed have limited financial and human resources. These constraints make it difficult to manage the procurement of VMMC commodities. Required commodities include a wide variety of items—from pharmaceuticals to medical supplies, incinerators to prefabricated surgical units [24]. 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 GUIDANCE DOCUMENT 5). An initial logistics assessment should be done to provide a clear understanding of the demand, capacity, and expectations of local sourcing practices and limitations.

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 six months prior to the beginning of services (see TOOL 9). Generally, the forecasting and planning exercise is taken on by the project manager in collaboration with the site manager(s) and procurement officers. Project managers, 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 TOOL 10). The Supply Chain Management System (SCMS) is a part of the President’s Emergency Plan for AIDS Relief (PEPFAR) and is administered by the United States Agency for International Development (USAID). SCMS provides a reliable, cost-effective, and secure supply of products for HIV/AIDS programs in PEPFAR-supported countries.

Procurement

Whether products are sourced locally or internationally, strong QA processes must be implemented when vetting suppliers to ensure that goods and pharmaceuticals procured meet US

government regulatory requirements and/or can be approved via USAID Automated Directives System (ADS) 312 (see TOOL 8). 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 full year, depending on manufacturer stock levels and lead times.

Steps of the Procurement Process

- *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 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. These specifications can be found in the SCMS catalog (see GUIDANCE DOCUMENT 3).
- *Creation of Price Request and Price Quote:* 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 TOOLS 6 and 7). 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. In order to minimize delays, VMMC program managers should complete the CLIENT AND RECIPIENT INFORMATION FORM as well as the SHIPPING INSTRUCTIONS FORM that are included in the tools section. 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 US 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/or expected client demand, and assuring the complete understanding of the VMMC program implementation plan and its needs for commodities. Communicating all of the site's needs up front will prevent having to repeat the steps above, which will contribute to delays.
- *Purchase Order/Sales Order Creation:* After the approval of the quote, the site manager(s) or procurement officer(s) can work with the project manager to develop a purchase order. This process should take anywhere from a couple of days to a couple of 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 available 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 100% accurate partner and destination information is critical in this step. This step can be problematic for newly launched VMMC programs that need to order a product before a supply chain and logistics plan has been developed for the program. However, shipments that move forward without accurate information can be delayed in the customs process for months.

- *Customs Pre-Clearance 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, 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 pre-clearance 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 from customs, it will be transported to the storage warehouse. The time required to complete this step can depend upon distance, mode of transportation, country, etc. 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 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 TOOL 9). These needs are identical at the program and at the individual site levels. Prior to the launch of a VMMC program, 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. For this purpose, a forecasting and supply planning exercise with multiple demand scenarios should be done with all partners at the program level at least six months prior to the beginning of services.

Decisions should be made regarding the parties who are 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 VMCMs 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 should be selected. Also, minimal storage capabilities, along with a closely monitored consumption system, should be in place.

VMMC Kits

Key components in commodity procurement include 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 “pack” of reusable surgical instruments that can be sterilized and reused (see GUIDANCE DOCUMENT 3). See Table 2 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 intentionally not been included, because these are medicines that often require entirely separate procedures for procuring, shipping, and importing into each PEPFAR country.

Table 2: Advantages and Disadvantages of Disposable versus Reusable VMMC Kits

	VMMC Kits with Disposable Instruments	VMMC Kits with Reusable Instruments
Advantages	<ul style="list-style-type: none"> ■ Ensure high-quality, sterile content in both non-hospital and hospital settings ■ Are logistically and operationally easier, especially in mobile outreach services ■ Reduce initial startup program costs ■ Eliminate autoclave maintenance, personnel, training, and other costs ■ Can combine consumables, disposable instruments, and even client education materials into one kit ■ Can be bundled to ease ordering and managing of supplies ■ Increase service delivery efficiency 	<ul style="list-style-type: none"> ■ Ensure high-quality, sterile content in both non-hospital and hospital settings ■ Well-maintained re-usable instruments are easier to use than disposable plastic and stainless steel instruments ■ Build health system capacity and infrastructure ■ Employ local personnel ■ Create less waste and there is less need for waste management procedures ■ Require fewer long-term resources to procure additional instruments
Disadvantages	<ul style="list-style-type: none"> ■ 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 having some contents pilfered, which could compromise the sterility of the remaining contents 	<ul style="list-style-type: none"> ■ Require additional staff time for cleaning, sterilizing, and packaging instruments, and 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

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. These items (see GUIDANCE DOCUMENT 3) can be divided into four types of 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

Case Study—Zimbabwe’s VMMC Commodities Logistics System

The Zimbabwe VMMC logistics system was designed in 2010 in response to the Ministry of Health and Child Welfare (MOHCW) plan to roll out VMMC services to more facilities after a successful pilot. The VMMC system was intended to work together with the antiretroviral (ARV) distribution system.

In 2012, eight fixed sites and various outreach teams are offering VMMC services. At least four people from each site are trained in the VMMC logistics system. The trained staff report using two specially designed forms that are completed every two months. The first one is the *Consumption and Requisition Form* that tracks how many consumables have been used and what stock remains at the fixed sites. The second form is the *Outreach Voucher* that tracks commodities taken out of fixed sites specifically for outreach purposes. From the essential logistics data reported on these forms, the logistics officer is able to make decisions regarding the need for new supplies.

Estimation of VMMC commodity needs is integrated into the MOHCW forecasting exercises where annual quantification is done at the beginning of the year with updates every trimester. The forecast is based on the targets for procedures guided by different criteria including historical procedures, country targets, infrastructure and personnel capacity, and budget considerations. However, an alternative, consumption-based forecast will be considered when the system matures and consumption data become more reliable. Current VMMC program campaigns can be seasonal and are country-specific, with aims to target certain populations at different times of the year. For this reason, commodity needs for these campaigns must still be estimated based on the targeted populations.