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

PEPFAR's Best Practices for Voluntary Medical Male Circumcision Site Operations

A service guide for site operations

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ABBREVIATIONS

ADS	Automated Directives System
AE	Adverse Event
AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral
CBT	Competency-Based Training
COP	Country Operational Plan
DHS	Demographic and Health Survey
EQA	External Quality Assurance
HCRW	Health Care Risk Waste
HCWM	Health Care Waste Management
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
HPV	Human Papillomavirus
HR	Human Resources
HTC	HIV Testing and Counseling
IEC	Information, Education, and Communication
IPC	Interpersonal Communication
M&E	Monitoring and Evaluation
MCHIP	Maternal and Child Health Integrated Program
MOH	Ministry of Health
MOHCW	Ministry of Health and Child Welfare
MOHSW	Ministry of Health and Social Welfare
MOU	Memorandum of Understanding
MOVE	Models for Optimizing Volume and Efficiency
NACP	National AIDS Control Program
NGO	Nongovernmental Organization
OVC	Orphans and Vulnerable Children
PEPFAR	The US President's Emergency Plan for AIDS Relief
PITC	Provider-Initiated Testing and Counseling
PMTCT	Prevention of Mother-to-Child Transmission
QA	Quality Assurance
RCT	Randomized Controlled Trial
SCMS	Supply Chain Management System
SD	Start Date
SOP	Standard Operating Procedure
STI	Sexually Transmitted Infection
TWG	Technical Working Group
UNAIDS	Joint United Nations Program on HIV/AIDS
USAID	United States Agency for International Development
VCT	Voluntary Counseling and Testing
VMMC	Voluntary Medical Male Circumcision
WHO	World Health Organization

MESSAGE FROM THE US GLOBAL AIDS COORDINATOR

Voluntary Medical Male Circumcision (VMMC) is a proven biomedical intervention that has the potential to save millions of lives and significant resources if it can be scaled up in high HIV prevalence regions where male circumcision is uncommon. The US President's Emergency Plan for AIDS Relief's (PEPFAR's) most recent guidelines highlight VMMC as one of the core biomedical prevention intervention activities alongside condom use, HIV testing and counseling, diagnosis and treatment of STIs, and ARV-based prevention. Recently, leaders from five international organizations (the World Health Organization, the Joint United Nations Programme on HIV/AIDS, PEPFAR, the Bill & Melinda Gates Foundation, and the World Bank, in consultation with national ministries of health) launched a strategic framework for action that will guide and ensure streamlined efforts to circumcise 20.3 million men in 14 countries in eastern and southern Africa by 2016. This framework, in conjunction with President Obama's renewed commitment to provide support to countries to successfully complete 4.7 million circumcisions by the end of 2013, necessitates the implementation of quality VMMC services at scale.

Providing VMMC quality services that meet WHO-defined standards and provide the WHO minimum package of services (HIV testing and counseling, active exclusion of STIs, provision and promotion of condoms, risk reduction counseling, and circumcision surgery) is no small feat. The planning, engagement of stakeholders, logistics, quality assurance, and service provision tasks need to be well planned and adequately addressed at the country, regional, district, and service levels. This document aims to provide PEPFAR implementing partners guidance and relevant approaches in the specific context of providing VMMC services at the *facility and/or VMMC site level*. The guide is aimed to help implementing partners provide high-quality services to ensure that the scale-up of VMMC is successful all the way from the site to the global level.

The development of this document has been a community effort by the many experts working in the field of VMMC for HIV Prevention. The document is unique in that it highlights various approaches, in context, that have been shown to be successful in the field. The development of this guide has been possible thanks to the various PEPFAR partners who provided data, specific approaches, and useful comments. I would like to acknowledge all the PEPFAR field offices (United States Agency for International Development, Centers for Disease Control and Prevention, Department of Defense) for providing input that has greatly enhanced the quality of this document. I would particularly like to acknowledge the PEPFAR Voluntary Medical Male Circumcision Technical Working Group. This document was developed under the technical leadership of Emmanuel Njeuhmeli of USAID and Jonathan Grund of CDC with support from Tigistu Adamu and Alice Christensen of MCHIP (PEPFAR through USAID-funded project managed by Jhpiego).

PEPFAR implementing partners have a vast task ahead of them to reach the goal of circumcising 20.3 million men by 2016. The rewards will be enormous with millions of lives saved and a tidal shift seen in the reduction of HIV incidence and prevalence. I encourage the use of this guide by implementers at the site service level. The guide is a tool that provides important guidance, highlights successful approaches, and describes many of the relevant pieces that make up the key steps in successful implementation of high-quality VMMC services. I trust that this guide will be a resource that can be readily used by PEPFAR partners as they continue to build upon their current successes in VMMC implementation.

Sincerely,

Ambassador Eric Goosby
US Global AIDS Coordinator

PEPFAR's Best Practices for Voluntary Medical Male Circumcision Site Operations

A BEST PRACTICES DOCUMENT FOR ESTABLISHING NEW VOLUNTARY MEDICAL MALE CIRCUMCISION (VMMC) SERVICES

Introduction

This document provides PEPFAR's implementing partners with a comprehensive and consistent process for establishing new Voluntary Medical Male Circumcision (VMMC) services for HIV prevention. It draws upon numerous documents developed by UNAIDS/World Health Organization (WHO) and the PEPFAR Voluntary Medical Male Circumcision Technical Working Group (VMMC TWG). This guide also builds on the experiences and materials from existing VMMC programs in southern and eastern Africa. *The scope of this document is limited to establishing and supporting quality VMMC services for HIV prevention at the facility or VMMC site level.* The necessary steps involved in scaling up VMMC services at the national, regional, and district levels are beyond the scope of this document. For a more comprehensive view of the key steps in a national VMMC program, see GUIDANCE DOCUMENT 1, WHO's OPERATIONAL GUIDANCE FOR SCALING UP MALE CIRCUMCISION SERVICES FOR HIV PREVENTION [1].

Background

VMMC reduces men's risk of acquiring HIV through heterosexual intercourse by approximately 60% [2–10]. As more men become circumcised, fewer will become infected with HIV. VMMC indirectly protects men's female sexual partners from HIV, because HIV-negative men cannot infect their female sexual partners. However, for HIV-positive men, VMMC does not reduce their risk of transmitting HIV to their sexual partners. Furthermore, if men who are already HIV-positive become circumcised, it will not reverse their HIV-positive status.

UNAIDS and PEPFAR have estimated that scaling up VMMC in men aged 15–49 years in 14 southern and eastern African countries will require 20.3 million circumcisions in five years in order to reach 80% coverage of the eligible population. Using this level of coverage over the next 15 years, mathematical modeling suggests there is the potential to avert up to 3.6 million new HIV infections and generate a potential cost savings of US $16.5 billion [11].

In addition to the reduction in risk of HIV acquisition among circumcised men, VMMC provides other health benefits to men and to women. Evidence shows that VMMC reduces some sexually transmitted infections (STIs), particularly ulcerative STIs, including chancroid, herpes, and syphilis, as well as balanitis, phimosis, and penile cancer [12, 13, 14]. One of the primary benefits of VMMC for women is its association with a reduction in penile human papillomavirus (HPV), which is associated with cervical cancer in female partners [13, 15]. As more men are circumcised, women's likelihood of sexual exposure to HIV decreases, and their risk of HIV infection also declines. The indirect protection for women is substantial; modeling at levels of 80% circumcision coverage shows an approximately equal number of HIV infections will be averted in women as in men after 15 years [11].

Although VMMC has been shown to significantly reduce men's risk of acquiring HIV via heterosexual intercourse, VMMC does not provide complete protection from HIV [2, 3, 4]. Because VMMC provides only partial protection from acquiring HIV [16], it is necessary for circumcised males to minimize any potential increased risky sexual behaviors following VMMC surgery (known as risk compensation) [4, 16–19]. Of note, behavioral data from two of the VMMC randomized controlled trials (RCTs) show that circumcised men were no more likely to engage in high-risk sexual practices than uncircumcised men [2, 3]. In a slight contrast, the RCT study in South Africa found that men enrolled in an RCT intervention group (circumcised men) reported an average of approximately one more sexual contact in the prior eight months compared to men in the control group (uncircumcised men) who had significantly more

sexual contacts [4]. In order to ensure that VMMC surgery is provided as part of a comprehensive HIV prevention package, WHO recommends that all VMMC clients receive the minimum package of services, including:

- HIV testing and counseling (HTC) (offer of)
- Screening and treatment for STIs
- Promotion and provision of male and female condoms
- Promotion of safer sex practices and risk reduction counseling
- Male circumcision (surgical removal of the foreskin)

In addition to WHO's minimum package of services, PEPFAR also recommends additional components that ensure high-quality VMMC services including:

- Identifying and implementing active linkages of HIV-positive clients to care and treatment services
- Assuring voluntarism and informed consent

Rationale for Developing a Best Practices Document for VMMC Services

VMMC is a surgical procedure that must be provided safely in order to minimize risks of clinical complications. VMMC surgery can be provided safely by different cadres of health care workers (depending on individual countries' defined regulatory scopes of work) in fixed or mobile settings that meet the quality assurance (QA) standards for infection prevention. VMMC services must be of the highest quality, and mechanisms must be in place for client follow-up and management of AEs. In some communities where VMMC is not commonly practiced, it is potentially a sensitive and controversial intervention. Given these possible sensitivities, extra care should be taken to ensure that communities are provided with complete information about, and sensitization to, VMMC.

Investing in a thorough and measured approach to establishing new VMMC services at each service delivery site will help to ensure that the clinical and the cultural considerations are addressed, minimizing potential delays that could negatively affect the program. Higher levels of local ownership and "buy-in" to providing VMMC services will also benefit the program [20]. This *Best Practices* document describes approaches that have been used to establish VMMC services successfully in numerous countries, while minimizing the risks and maximizing the quality and benefits of the program.

This guide is designed primarily as a reference tool for PEPFAR-funded organizations that are planning, implementing, or evaluating VMMC programs. Each specific topic is a stand-alone section that includes an overview, timeline, useful tools, references to WHO-endorsed guidance, and relevant case studies. The guide is accompanied by a resource document that contains specific tools and resources. These tools and resources are referenced in each section and are also provided on a CD-ROM.

Figure 1 below provides a schematic representation of all the components needed to implement a comprehensive and successful VMMC program. This guide will address most of the components shown in this figure.

Figure 1: Sample Implementation Puzzle Piece Framework

This sample implementation "puzzle piece" framework illustrates the various components that are involved in VMMC service delivery. Each piece is an essential part of the program and is dependent on other pieces; some puzzle pieces may occur concurrently while others may occur sequentially. Please refer to Figure 2 for the timeline component of each of the puzzle pieces. The goal of a program is to address all the pieces to ensure high-quality VMMC services. This document provides guidance on each puzzle piece and also draws the broader picture by pointing out the important linkages among the pieces.

(Items underlined are addressed in this guide.)

Figure 2: Illustrative Timeline for Launching New VMMC Services

Months 1–12 timeline chart showing the following activities:

- Services Begin (star marker at Month 4)
- 1. Service Site Selection
- 2. Service Site Planning
- 3. Service Site Preparation
- 4. Procurement of Commodities*
- 5. Creating Demand
- 6. VMMC Skills Training
  - Training for Community Mobilization Partners
  - VMMC Counseling Training
  - VMMC Clinical Skills Training
- 7. Implementation of WHO Minimum Service Package
- 8. Support Launch of VMMC Services
- 9. Training VMMC Supervisors**
- 10. Adverse Events Management, Monitoring, and Reporting
- 11. Routine Monitoring, Reporting, and Evaluation
- 12. Special Studies (As Needed)
- 13. Internal and External Quality Assurance
  - Internal Quality Assurance
  - External Quality Assurance
- 14. Voluntarism, Informed Consent, and Reimbursement
- 15. Health Care Waste Management

* Forecasting and supply planning exercise with multiple demand scenarios should be done with all partners at the program level at least 6 months prior to the beginning of services. 3–4 months additional lead time is needed for mobile sites.

** If VMMC Supervisors will assure the support for the launch of VMMC services, they should be trained prior to training the VMMC providers; if not, they can be trained closer to beginning their role in supervision.

Estimate about 4 months to launch of services at a brand new site (depending on how long it takes to complete Service Site Strengthening).

Operational Guidelines

The key steps, or phases, covered in this *Best Practices* document are outlined in Figure 2 above, as well as in a table format with more detail in Appendix 1. The focus of this guide is on VMMC service delivery and the components associated with making a VMMC program operational.

It is essential that the training of all VMMC providers and staff has been conducted prior to the launch of VMMC services at the site. It is also important that client demand for VMMC has been generated to coincide with the launch of service provision. Equally, it is critical to equip VMMC teams with immediate, on-site logistical and technical support to ensure the smooth launch of services. This is important so that VMMC providers and staff can apply their new skills shortly after training. Ongoing supportive supervision, coupled with routine monitoring and evaluation (M&E) and targeted studies or evaluations, will ensure delivery of high-quality VMMC services. This *Best Practices* document systematically describes all of the essential elements for successful implementation of VMMC services.

1. Service Site Selection

Timeline—Site selection occurs in the first month of the timeline.

Useful Tools	1	VMMC Site Selection Criteria Tool
	2	VMMC Site Readiness and Preparation Tool
Useful International Guidance Documents	1	Operational Guidance for Scaling Up Male Circumcision Services for HIV Prevention

Objective(s): To select appropriate sites to provide VMMC services

Description: Site selection involves working with the Ministry of Health (MOH) and local authorities to identify locations that would be most appropriate for offering VMMC services. Refer to TOOLS 1 and 2, and GUIDANCE DOCUMENT 1. These resources can help guide site selection and setup.

Information on HIV prevalence and male circumcision prevalence, which can help prioritize VMMC sites in specific regions, can be obtained from nationally published documents such as Demographic and Health Surveys (DHSs) and other published research. If other data are available (e.g., mapping of available services, site inspections, and assessments), they should be consulted for additional site-specific information. The community and local community organizations must be integrally involved in the site selection process. Adhering to clear criteria for site selection is helpful, as is fostering strategic partnerships and productive working relationships among health facility staff and implementing partners.

Mobile units can also be used to provide VMMC services in locations that have limited health care facilities and in catchment areas that have little or no existing infrastructure.

Some suggested criteria and/or considerations for site selection include (but are not limited to):
- The prevalence of HIV and male circumcision in the catchment area
- The size and density of the catchment population
- Sub-district, district, provincial, and national support for selected site or area (for fixed or mobile services)
- An estimate of VMMC need (based on estimated male circumcision prevalence, HIV prevalence)
- Expected demand for VMMC services
- Potential physical space that can be dedicated (temporarily or permanently) to VMMC services

- Presence of other high-volume VMMC services in the area, and ability to coordinate resources and recruitment to avoid competition for clients
- Existing infrastructure and equipment, availability of skilled human resources
- Level of support of managers and service providers
- Accessibility of sites/facilities by the target population
- The type(s) of facilities available
- Space with potential for good client flow among the various services
- Referral networks:
  - Services and facilities that can refer potential clients for VMMC. These include:
    - Emergency services
    - Employer or worksite Occupational Health Centers
    - Voluntary Counseling and Testing (VCT) Centers
    - Primary health care clinics
    - Schools
    - Community outreach services
  - Service linkage and referral from VMMC to additional services. Facilities available for care and treatment, post-operative care, and support/AE management (see Section 10) may include:
    - HIV care and treatment sites for those who test HIV-positive
    - Clinics able to perform post-operative care
    - Regional, tertiary hospitals—AE management
- Transport routes that ensure coverage of the catchment area, identifying pick-up and delivery points
- Availability of equipment and supplies for VMMC services

Options for VMMC Services
Various site options, service delivery models, and staffing options are available for the delivery of VMMC services. These should be chosen based on the specific needs of the community and the VMMC program. Below is a description of various options that can be implemented in different settings, based on the VMMC program, geographical location logistics, seasonality demands, and other external factors. It is important to review the following three specific components when determining the best way to implement VMMC sites.

1. Determine the site options
   a. Fixed sites
   b. Mobile sites
   c. Outreach sites
2. Determine the type of service delivery
   a. Regular service delivery (offered throughout the year rather than at specific times)
   b. Campaign service delivery (offered during specific weeks/months)
3. Determine the staffing options
   a. Determine what human resources (HR) are available
   b. Determine service delivery model(s) (task shifting, Models for Optimizing Volume and Efficiency [MOVE], etc.)
   c. Calculate HR needs

There are three different types of VMMC sites (fixed, mobile, and outreach). These three types of sites can be mixed and matched to serve the community most effectively within the constraints of the program. The suggestions below are not prescriptive, but need to be matched to the resources that are available and linked with the supply and demand for services. (For more information on determining site options with relevance to creating demand, see Section 5.)

1) **Determine the Site Options**
    a) **Fixed sites** are permanent structures—often located near or within existing health care facilities—that offer VMMC on a continuous basis. Using fixed sites for VMMC service delivery may be most appropriate in urban areas with high population density, substantial VMMC client demand, and easy accessibility. Fixed sites may also serve as a hub for multiple mobile units. Fixed sites need to dedicate adequate space to accommodate all of the components of VMMC services: reception, waiting area, private counseling rooms, surgical theater, post-operative care, and follow-up review areas. Existing fixed sites often lack space to accommodate all the elements of service delivery, or cannot dedicate existing space. In these instances, additional space needs to be created by using semi-permanent structures or tents.

    b) **Mobile sites** are sites where the commodities and staff are actually mobile (moving to follow demand and/or supplement existing services). Mobile sites can provide services out of a health center (i.e., co-located with other services) or can be an outreach site. Mobile sites may be most appropriate in rural areas or communities that are not expected to have high demand for VMMC services, in areas that have high client demand at certain times of the year, or when a VMMC campaign temporarily increases demand. Mobile sites are usually temporary structures, often tents and prefabricated structures (see Figure 3 below).
        i. **Basic tents** are easy to install and are movable, though they may have poor air circulation and generally do not remain durable for long periods of time. These tents are most often used for HTC services at the VMMC site. Although tents can provide very flexible space for service provision when they are present, if adequate lead time is not planned, procuring tents can pose a significant delay to programs.

        Additional uses for tents include:

        - Creating extra space at an existing fixed health care facility.

        - Preventing bottlenecks in service delivery. For instance, a mobile structure for HTC services, set up adjacent to the fixed site, can provide a space where clients can be tested without crowding the fixed site.

        - Creating extra space dedicated solely for VMMC surgery at a fixed site.

        - Performing follow-up visits or group education. Smaller tents can be set up in the vicinity of the fixed site for this purpose.

        ii. **Prefabricated structures** are sturdier and more durable than tents, and they are most suitable for locations where a high volume of VMMC clients is expected. Prefabricated, semi-permanent structures can provide space for other medical services when VMMC services are no longer needed. These structures require significant lead time to ensure proper installation. Cranes may be needed to deliver prefabricated structures and to move them once they are set, given that foundations are needed, and the overall space within the structure is not as flexible as in tents.

Figure 3: Examples of a Medical Examination Room and Tents

c) **Outreach sites** can be used during times of high demand for VMMC, such as short-term campaigns. Outreach sites are generally small sites that provide VMMC services for a temporary time period in rural areas and in areas that are "hard to reach." Outreach sites can be permanent structures (e.g., primary clinic, school, community center), modified for VMMC purposes. Tents or prefabricated structures may be used to increase available space and allow more clients to receive VMMC services in sites that may be rural and far from a fixed site. A "hub and spoke" approach can be used, selecting hubs that act as the headquarters (fixed sites) with various "spokes" (outreach sites) that can be set up in lower-level facilities, non-health facilities, or mobile sites. Outreach sites are more flexible, as they can be placed in an area until it reaches saturation, and then moved to another location. Outreach sites are often supplied by a fixed site from which goods are transported on a daily or weekly basis.

2) **Determine the Type of Service Delivery**
   a) **Routine service delivery** ensures the availability of VMMC services at existing health care facilities, outreach sites, and mobile sites year round. Although space within a facility may be dedicated for VMMC services, the services are integrated with the facility and offered consistently throughout the year. Referral networks are established and in place and clients are referred to and from other services and facilities. Client volume is typically steady, so HR and commodity needs are at a consistent level throughout the year.

   b) **Campaign service delivery** provides VMMC services in high volume for short periods of time. With campaign service delivery, HR and commodities are dedicated for the duration of the campaigns. Demand creation and community sensitization are crucial components to ensure a high volume of demand for VMMC services during the campaign period. Services are often offered on consecutive days for a specified time period to capture as many clients as possible. Campaigns are often designed to target certain populations (e.g., during school holidays to provide VMMC to adolescents, or during certain times of year to align with cultural practices or traditions). Campaigns can also be used to "kick start" services in a district or region. Campaigns can be effective in attracting large numbers of VMMC clients, but considerable logistical planning is needed to ensure adequacy of sites, staff, clients, and commodities. For more information on effective campaigns and their impact on provision of services, see the article "Voluntary Medical Male Circumcision: Translating Research into the Rapid Expansion of Services in Kenya, 2008–2011" [21] and "Voluntary Medical Male Circumcision: Matching Demand and Supply with Quality and Efficiency in a High-Volume Campaign in Iringa Region, Tanzania" [22].

3) Determine the Staffing Options

a) **The HR staffing lists** that follow (see Table 1 below) are suggested for fixed sites where demand is consistent. These suggestions would not apply to sites where demand fluctuates with seasonality, school holidays, etc. Staffing is not prescribed and should be modified and adjusted, based on the volume of clients and the country context. Innovative ways to address HR constraints in VMMC programs include using surgical efficiencies, non-surgical efficiencies, task-shifting and task-sharing, temporary redeployment of the public sector via task shifting, and volunteer medical staff from other countries [23].

Table 1: Human Resource Staffing Options for High, Middle, and Low Volume Sites

Items	High Volume Sites	Middle Volume Sites	Low Volume Sites
Beds	8	4	Less than 4
VMMCs performed per day	Greater than 80 (with task sharing)	30–80 (with task sharing)	Less than 30
Site Manager	1	1	Shared role
VMMC Providers[1]	2	1	1
Nurses[2]	8	4	Shared role
Theater Assistant—"suture nurse"	1	1	1
Post-operative Care Nurse	1	1	Shared role
Hygienist/Cleaner/Infection Prevention Officer	1	1	Shared Role
Counselors—can overlap with trained nurses for efficiency	2 (minimum)	1 (minimum)	Shared role
Expert Clients	2	1	N/A
Community Health Workers	8–10	5–8	1–4
Runner	1	1	Shared role
Data Clerk	1	1	Shared Role
Receptionist	1	1	Shared role
Driver (for mobile sites)	1	1	N/A

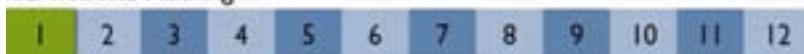**Case Study—Service Site Selection in South Africa**

Selection of fixed sites has been a process that occurs in consultation with the South African government. The focus has been on looking for fixed sites in high-density population areas that have reliable transport access. The objective has been to utilize the limited service delivery resources by locating initial fixed sites in the most accessible areas possible. The service delivery model is a hybrid (or mixed model) in which a fixed site is combined with mobile sites that are used for outreach. This specific hybrid establishes central, easily accessible, high-volume fixed sites capable of performing 50 to 100 VMMCs per day at each site. During campaigns and busy periods, this fixed site is the hub of activity and conducts large numbers of VMMC procedures. In periods between campaigns and during holidays, the fixed site continues to function with a basic staff team. During these slower periods, VMMC numbers decrease at the high-volume center to around 20 to 25 VMMCs per day. The additional center staff members are then deployed to cover a wider geographic range, and a number of mobile sites become operational. Generally, these mobile sites are low volume, and perform around 10 to 15 VMMCS per day. This mixed model ensures steady performance and delivery of VMMC targets throughout the year.

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[1] VMMC Providers are dedicated to the actual procedure: removal of the foreskin. These providers can represent a variety of health care worker cadres, depending on the laws by which these cadres are regulated.
[2] Nurses will perform a variety of tasks including documentation, assisting the VMMC Provider, prepping the room, and prepping the patient for the procedure. Depending on the country context, VMMC assistants may be doctors, nurses, clinical officers, or medical officers.

2. Service Site Planning

Service Site Planning

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |

Useful Tools	2 VMMC Site Readiness and Preparation Tool 3 VMMC Site Action Plan 4 VMMC Site Assessment Tool 5 Community Asset Mapping Figure 4: VMMC Client Flow Diagram
Useful International Guidance Documents	2 Considerations for Implementing Models for Optimizing the Volume and Efficiency of Male Circumcision Services, 2010 3 Supply Chain Management System (SCMS) E-catalog including all Male Circumcision Kit Options 4 Male Circumcision Waste Management Plan

Objective(s):

- To develop shared understanding, ownership, and support among the facility management, administration, counselors, clinicians, and the community
- To create a site preparation action plan for providing the minimum package of safe VMMC services

Description: Once a site has been selected, a thorough approach to site preparation and site strengthening can greatly affect a VMMC program's success. Conducting a thorough site assessment, including a site management orientation, will guide what is needed to get the site "operational" (see TOOLS 2 and 3). Site preparation has two primary objectives: 1) to develop ownership of, and support for, the VMMC site by site managers and community members; and 2) to agree on a site preparation action plan for developing and providing a minimum package of safe VMMC services.

Normally, the service site planning activity utilizes a designated Facility Management Team composed of hospital director, director of clinical care, sister-in-charge or chief nursing officer, the key administrative staff responsible for budgeting and procurement, and those clinical staff who would be expected to lead the provision of services. In addition, other cadres of health workers (e.g., community health workers, home-based care workers, health promoters) can be included in the orientation because they can be used to aid implementation. Some countries have utilized community health workers to serve as mobilizers for demand creation and client follow-up visits.

When conducting the site assessment, it is important to include the appropriate authorities and technical implementing partners. It is also vital to conduct a thorough orientation on VMMC for HIV prevention for site staff, prior to the assessment, so that all members are clear on the purpose of VMMC. The orientation can include:

- A review of the national VMMC strategy
- Specifics related to the site and the plan for services (regular versus campaign services, outreach sites, targeted numbers for VMMC, existing cultural beliefs, any research conducted or planned, etc.)
- How the site fits into the implementation plan

After the orientation has been conducted and team members are aware of the goals and layout of the program, the general site assessment can begin. The site assessment can be conducted by the Facility Management Team, or just certain team members. It is crucial that a site manager is designated and is an integral part of the site assessment process. The site assessment should evaluate (see TOOL 4):

- The current state of basic services (e.g., infection prevention, waste disposal, and M&E) (see GUIDANCE DOCUMENT 4)
- The space identified for VMMC services and the map of client flow (see GUIDANCE DOCUMENT 2 and Figure 4)
- The catchment area, and identify potential feeder clinics and points for post-operative care and support
- Existing community health workers or other health care worker cadres to be trained in VMMC service delivery (demand creation, VMMC counseling, clinical procedures, etc.)
- The capacity of feeder clinics and points for post-operative care to manage AEs that require hospitalization
- Transport routes to ensure that the catchment area is covered, and that pick-up and delivery points are identified
- The equipment and the current supply availability specific to VMMC services (what the site currently has and what the gaps are) (see GUIDANCE DOCUMENT 3)

The site assessment should also:

- Identify additional service outlets and establish linkages and referral centers that could be used to provide:
  - Community-based information, education, and communication (IEC); group education; community-based HTC; and community-based client screening
  - VMMC messages—about where VMMC information is available, where VMMC services are provided, and where clients are referred (outpatient departments, STI clinics, antenatal clinics, family planning clinics)
  - Referrals to care and treatment—VMMC clients may be referred for additional care and treatment, HIV prevention, HIV care and treatment, STI management, and reproductive health services
  - Screening and follow-up of clients based outside the catchment area
- Identify the key personnel who will be involved at the various stages of the VMMC process: management, communication, and demand creation; booking, reception, and registration; HTC; pre-procedure clinical screening; VMMC procedure; post-operative care and counseling; reviews and follow-up services; data management; waste management (see GUIDANCE DOCUMENT 4); infection prevention, etc.
- Reach agreement with the site management on developing signage and branding that can be placed in defined locations—within and outside the facility—to direct prospective clients to VMMC-related services
- Identify and assess locations, if temporary space is needed

Based on the findings of this assessment, the team should work together to develop a detailed VMMC SITE ACTION PLAN (see TOOL 3) to get the site ready to provide safe VMMC services. The Site Action Plan provides a clear outline of what must be completed so that the site is ready to provide VMMC services (e.g., HR to be hired, commodities to be ordered, renovations or restructuring of space to be completed, etc.). This Site Action Plan can be used as a task log that outlines specific activities and

timelines, and designates staff members who are responsible for ensuring that each task is complete. The site preparation action plan should be based on a clear understanding of how the services will be provided, and it should link community demand creation (see Section 5) with clinical service provision (see Section 7). This Site Action Plan should be specific and time bound, and it should clearly identify who is responsible for achieving specific actions, the resources required, and the source of support. At this stage, the Site Action Plan may be useful in developing an agreement between partners, clarifying roles and responsibilities, and ensuring that the planned timeline is reasonable.

After the VMMC Site Assessment has been conducted and the Site Action Plan has been developed, it can be useful to conduct a general orientation for all staff at the facility. This orientation, which is more general than the initial facility management team orientation, is used to sensitize all staff to VMMC for HIV prevention services, and includes an overview of how and when these services will be offered at the facility. Site orientation helps to reinforce ownership by the health facility staff and management team, and ensures that key concepts concerning VMMC are internalized. In addition, site orientation minimizes the chances that misinformation will be disseminated while the site preparation action plan activities are getting started.

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Using Community Mapping for Site Assessments

COMMUNITY ASSET MAPPING is a tool that can be used to gather information as part of the site assessment process. Many programs have found mapping to be useful in determining what is available in the community and how to engage these resources to aid VMMC programming (see TOOL 5 for a detailed example of Community Mapping).

Community Mapping Process—Create a document that outlines available resources, roles and responsibilities, opportunities, and challenges. This document will help identify potential community partners including community-based organizations; faith-based organizations; men's, women's, and youth organizations; and the local media that can be drawn upon to assist with community advocacy, mobilization, and preparedness for the VMMC program. The mapping will also assist in identifying community-based organizations, nongovernmental organizations (NGOs), etc. that can provide various components of the VMMC program in the community (e.g., group education, community-based HTC, pre-operative screening, post-operative care, and follow-up) and that can set up the appropriate referral systems. Establishing organizational links within the community will reduce the congestion at health facilities and, thereby, increase the efficiency of services as well as client satisfaction.

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Case Study—Tanzania's Site Preparation Action Plan Tool Development

Tanzania started its VMMC program in September 2009, through the VMMC Technical Working Group, under the leadership of the Ministry of Health and Social Welfare (MOHSW). Three pilot regions were selected to act as demonstration sites for program implementation so that lessons learned from the pilot could guide the scale-up of safe VMMC in the other priority regions.

The PEPFAR-funded program in this pilot phase was tasked with designing tools and guidelines, in collaboration with other partners, to ensure smooth implementation of the program. At that point, national guidelines did not exist. The program developed guidance on planning service initiation in a new site.

The guidance document provides an outline of the phases needed for service site planning. In the initial phase of this activity, all key stakeholders who are going to be involved in establishing the site—including frontline regional or district leadership, cultural and religious leaders, and other relevant stakeholders—are briefed about the services during a short orientation meeting.

Then management and key staff at the health care facility level are involved in planning for actual VMMC service delivery so that they own the program. It is important to take facility managers through all the steps in VMMC service provision. In this way, these facility-level stakeholders can appreciate the amount of space needed—not only to offer services comprehensively, but also efficiently. For example, site planners need to consider the layout of surgical space, multiple surgical bays, client flow, etc. Following this discussion, a site assessment is conducted to map out all the rooms required for service provision and gather all the other relevant information.

After the initial assessment phase, an action plan is established jointly by the program managers and the facility management, and roles and responsibilities are assigned to address any deficiencies found in the initial assessment. Joint action planning ensures that the facility management team is part of the whole process, and further commits them to supply their resources (including HR) to the VMMC program.

Service site planning is a crucial step that serves as an entry point to successful launch of services. By gauging management's commitment to and concerns about VMMC service provision, this activity also saves time and money. Site planning determines whether facility management supports the initiation of VMMC services, and discerns any hesitation management may have about starting these services at the site (e.g., limited space or insufficient HR).

The Site Action Plan can further serve as a reference document while site preparation activities get under way. It provides an overview of what is needed to enable a particular site to initiate safe VMMC services, and determines costs and activities that must be considered for a specific VMMC site.

3. Service Site Preparation

Useful Tools	Appendix 2: VMMC Service Site Preparation Planning Template Figure 4: VMMC Client Flow Diagram
Useful International Guidance Documents	3 Supply Chain Management System (SCMS) E-catalog including all Male Circumcision Kit Options

Objective(s):   To prepare the site so it is ready to provide VMMC services that meet the minimum standards, and services can be launched once the staff training is completed

Description: It is essential that a site's facilities, equipment, and commodities (see GUIDANCE DOCUMENT 3) are ready to provide VMMC services BEFORE staff are trained to provide VMMC services. Training is most effective when the learned skills are put to use immediately after training. Staff should finish their training, and then be transitioned into service delivery without delay. Starting services before a site is fully operational runs the risk of compromising the quality of services provided and creating potential bottlenecks, with imbalances of supply and demand for VMMC services. Based on the site strengthening plan developed collaboratively during site planning in Section 2 above, all the necessary activities should be carried out and completed prior to scheduling training and launching services. Various activities may be required, such as facility repairs or reorganization, procurement of equipment and supplies, shifting of staff rotations and duties or hiring additional dedicated staff, and specific training (e.g., training in infection prevention). All the parties involved should report on their responsibilities, and one qualified individual (often the site manager) should be charged with verifying that all the necessary actions are completed and that the site is ready to start providing VMMC services (see Appendix 2).

The overarching goal of site preparation and design is to ensure efficient client flow. Client flow should be unidirectional and allow clients to flow—from education and HTC to discharge—with ease (see Figure 4). With good planning, existing space can often be modified—with little infrastructural change—to maximize utilization of space and improve client flow.

Figure 4: VMMC Client Flow Diagram

A possible large fixed clinic site configuration that optimizes client flow

Note the client flow is unidirectional.
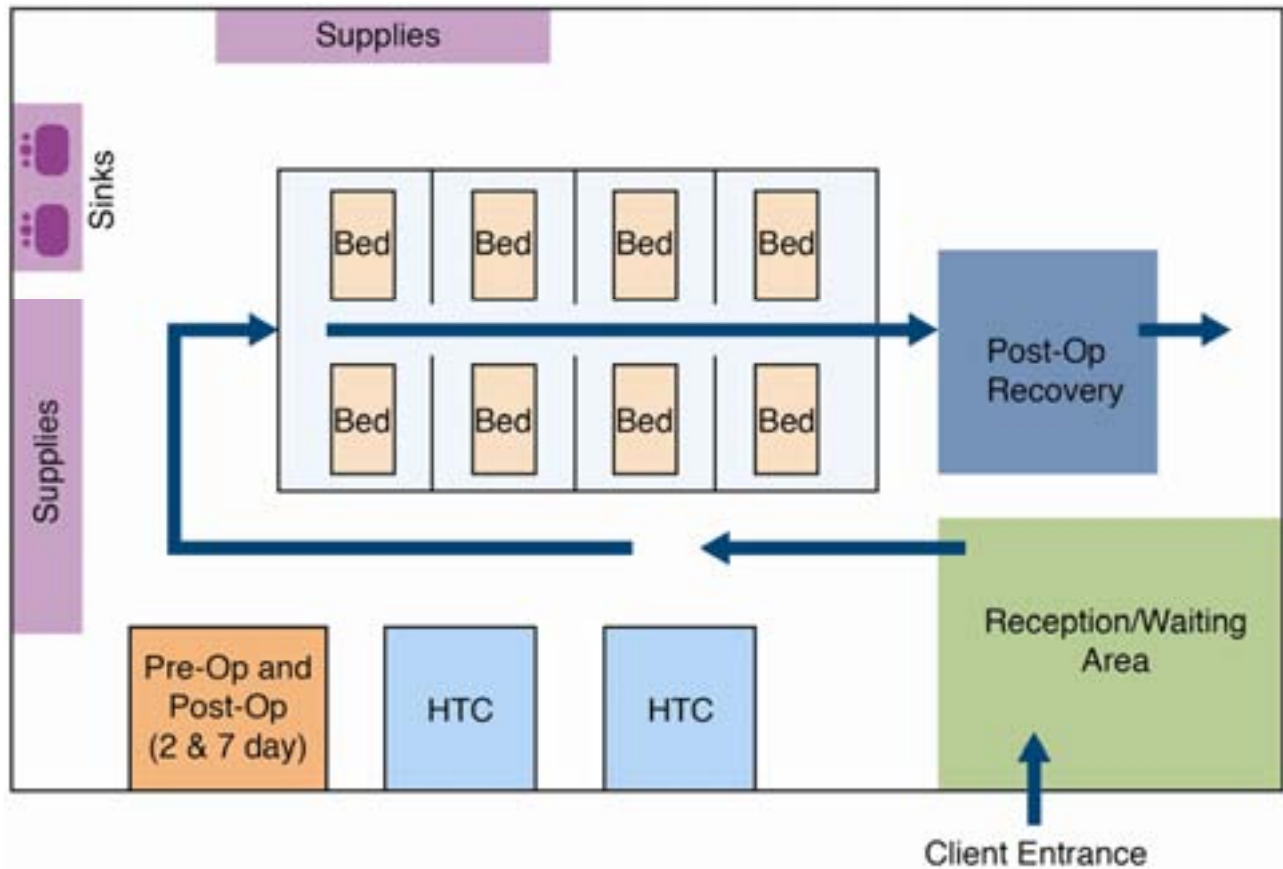
Tips for Organizing Facility Space for VMMC services
- Client flow should be unidirectional.
- Recovery space should accommodate more clients than surgical space. Because recovery time can be longer than procedure time, bottlenecks can occur if recovery space is inadequate.
- If space permits, client follow-up reviews should be conducted in an area that is separate from surgical areas. Separating the two areas will simplify client flow and reduce stress to staff.

Case Study—Site Preparation for Tanzania's Lake Victoria Islands

Tanzania's VMMC activities were expanded into the Lake Victoria Islands of Kagera region, where HIV prevalence was estimated to be 10–20% and male circumcision prevalence was estimated at less than 38% in 2010. The VMMC campaign targets about 20 inhabited islands, scattered in Muleba District, that have a highly mobile male population of approximately 25,000.

These hard-to-reach locations pose significant logistical challenges for providing VMMC outreach services, because locally made wooden boats with outboard engines are the primary means of transport. These islands have no electricity and require three to nine hours of travel time from the mainland. Health care facilities are limited on the islands because only two faith-based primary health facilities serve all 20 islands.

These islands are primarily inhabited by fishermen, though most fishermen maintain permanent homes on the mainland. The fishing business is lucrative, and many businessmen control significant economic resources on the islands, which likely contribute to the reported high availability of commercial sex on the islands. The remoteness of these islands has also been a substantial barrier to providing government services that meet the standards provided on the mainland. Local island leaders play a dominant role in providing social cohesion, basic services, and security to island residents.

Therefore, an essential first step to providing VMMC in these locations is sensitizing local leaders so that they will accept "outsiders" on the islands and facilitate the recruitment of islanders for services, logistics, and security. Preliminary visits were made to selected islands, during which the local government leaders, fish lords, and other influential people were sensitized to VMMC. These visits were followed by community sensitization meetings that aimed to engage the community in relaying VMMC promotional messages. Local leaders helped to facilitate these meetings and were active participants in promoting VMMC services to the islands' residents.

Some islands could provide a dispensary (clinic) or other suitable physical structure that could be converted into a fully equipped VMMC site during the campaign, while other islands had no available infrastructure. Because electricity is not available on any of the islands, solar panel systems for lighting and a generator for autoclaving were brought from the mainland to support VMMC services. All other materials for the campaign—including examination beds, reusable surgical kits, all consumables and supplies for the entire campaign, information, education, and communication (IEC) materials, two autoclave machine, and two 500-liter plastic water reserving tanks—were ferried from the mainland prior to service provision. PEPFAR provided two tents, which were fabricated to serve as a VMMC mobile clinic. Community members provided chlorine-treated water from the lake for daily non-drinking use at the clinic. In collaboration with local government authorities, an area at a safe distance from community neighborhoods was allocated where medical waste could be incinerated. For the duration of the campaign, experienced VMMC providers from hospitals on the mainland camped in the islands' guest houses.
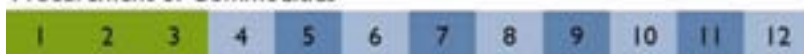

Setting up the VMMC mobile clinic

VMMC mobile clinic

Between October 2010 and November 2011, five VMMC campaigns were completed on these islands, during which 3,995 men received VMMC services. The AE rate was minimal (0.5%). This model served as a platform to enable the introduction of other HIV services including prevention of mother-to-child transmission (PMTCT), care, and treatment.

4. Procurement of Commodities

Procurement of Commodities*

| I | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |

* 3–4 months additional lead time for temporary sites

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

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

PEPFAR's Best Practices for Voluntary Medical Male Circumcision Site Operations

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 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 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 DOCEMENT 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	- 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	- 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	- 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	- 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.

5. Creating Demand

Creating Demand

1	2	3	4	5	6	7	8	9	10	11	12

Useful Tools	11 Communication Strategy for Voluntary Medical Male Circumcision in Kenya Appendix 3: Phases of VMMC-Related Communication 12 Communication Materials Adaptation Guide 13 A Guide to Working with the Media to Promote VMMC in Kenya 14 VMMC Video Discussion Guide
Useful International Guidance Documents	6 VMMC Demand Creation Toolkit

Objective(s):

- To provide the community with accurate and complete information about VMMC, including its potential for reducing the risk of HIV infections and other benefits
- To identify and correct any myths and misconceptions about VMMC
- To build demand for VMMC and provide all information necessary for informed consent among eligible men and ensure that the supply of services (e.g., sufficient equipment, consumables, and human resources) is appropriate to meet the demand for services

Description: Advocacy, community awareness, and formal community mobilization activities are critical components of VMMC demand creation and coordination with service delivery (see TOOLS 11, 12, 13, and 14). One of the first priorities in the VMMC program should be to enlist local leaders to help engage the community. The most successful VMMC programs have spent at least six months in gaining key stakeholder support for new VMMC services (stakeholder sensitization) [22]. Once key stakeholders—including MOH officials, administrators, businesses, traditional leaders, and other public opinion leaders—understand and support VMMC services, community sensitization activities addressing the broader community may be rolled out. Sensitization activities are used to educate the community about VMMC and its benefits. Sensitization activities can include radio interviews, newspaper articles highlighting VMMC, and general education activities within the community (community dialogues and education through counselors and health promoters). Such communication should not only emphasize accurate understanding of VMMC, but should also promote safer sexual behaviors (see GUIDANCE DOCUMENT 6). It may also be relevant to explore gender norms, including issues around VMMC and masculinity, including women's views, as well as the influence of norms upon sexual decision-making. Depending on the country and circumstances, informed demand creation activities that allow for community interaction—including small group activities, debates, panel discussions, or radio programs—may be most appropriate. Sensitization activities must begin prior to the launch of VMMC services and will likely need to continue, at least periodically, while services are available. Often local stakeholders will know the best sensitization approaches, and these stakeholders should be consulted throughout this stage to ensure that communication is targeted to the correct audiences most efficiently and appropriately. The inclusion of the MOH and other key stakeholders through all stages—from planning (see Section 2), to community sensitization, and other demand creation activities—is vital. Challenging as it may be, it is important to develop a comprehensive implementation and budget plan before going ahead [23]. It is essential that all aspects of service delivery at a site be ready to meet the demand that is created.

Once the timing for the launch of services is established, formal mobilization activities (which may include community meetings, door-to-door visits, radio ads, group education, road shows, and drama performances) can be started. These activities should be directly linked to the startup of VMMC services, and should include information on when and where to go for VMMC. These formal mobilization activities should begin at least two weeks before the launch of VMMC services. Well-coordinated mobilization can help reduce pressure on VMMC services by allowing time for group education or mobile HTC services in advance of VMMC. These timesaving measures will allow for more efficient provision of services at the VMMC sites. Community mobilization partners need to be trained in correct and consistent messages about VMMC, HIV prevention, and men's health in general. Service provision and mobilization programs can be continually modified and re-balanced to ensure that supply matches demand. VMMC education, counseling, and other information provided at the VMMC site should expand on information the client may have already received. The messaging should complement community awareness and mobilization messaging, and provide sufficient detail to assure informed consent for VMMC. Successful community demand creation requires the following elements:

- Mobilization that is well-timed and scaled to align with the availability of services, so that client demand does not outpace service provider supply

- Outreach through multiple channels (including mass media) that engages the target population including their partners, guardians, workplace, and individuals or other groups that can influence the VMMC decision

- Tailored messages and communication channels that resonate with younger and older men, both in and outside of relationships

- Comprehensible brochures and leaflets printed in the local language, targeted to specific audiences

- Materials that clearly direct potential clients to local VMMC service sites

- Recruitment of satisfied clients to encourage their peers to undergo VMMC (a tool that can add to community sensitization and mobilization)

- Monitoring community mobilization for message quality and consistency; and to allow for prioritization of clients who have already received community-based counseling, as well as follow-up with potential clients who do not present for services

- Communication campaigns that can be adjusted, as needed, to match the amount of services that can be provided; and similarly, services that can be scaled up to keep pace with the demand created by the advocacy, sensitization, and mobilization

The following activities can be used to monitor communication:

- Track the number of VMMC communication materials produced and disseminated (e.g., communication guides and materials distributed to community mobilizers).

- Identify salient issues as new activities and products are planned (e.g., formative research that can guide communication strategies). The issues identified can be used to monitor changes that need to happen in current communication plans as well as determine new, innovative, or alternative strategies. In Tanzania, *The Unpeeled Mango: Formative Assessment of Adult Male Circumcision Opinions/Prefere*nces helped guide the program's communication strategies [25]. The assessment was used to design a communications campaign using the local slang term for the foreskin "Dondosha mkonosweta! Kitendo rahisi, sasa ni bure!" ("Take off your sweater sleeve! Easy to do, now free!") [26].

- Differentiate paid advertising from unpaid coverage (e.g., public service announcements, news stories). Tracking the different advertising media can determine successful strategies and direct resources allocation to ensure that money is well-spent while reaching the targeted populations efficiently.

- Exploring the development of a media intensity index (i.e., a means of quantifying the volume of materials produced and disseminated). Media indexes are important to track how well communication plans are being implemented. By tracking production and dissemination of communication materials, programs can appropriately ensure that they are efficient and successful in the media campaigns.

Demand creation is part of a broader package of communication messages surrounding VMMC (see Appendix 3); these other communication messages need to be addressed as part of the comprehensive communication strategy in the context of VMMC.

Case Study—Zimbabwe's Matching Supply and Demand

Advocacy activities targeting community leaders—including traditional chiefs, headmen, school directors, religious and business leaders—are implemented as part of the initial steps in creating demand for VMMC at the community level in Zimbabwe. The majority of community leaders who have been sensitized to VMMC have been instrumental in motivating their communities to access VMMC services. Trained community volunteers and youth organizations move from door to door conducting discussions on VMMC, using drama, music, and dance to inform potential clients of the benefits of VMMC and to dispel any myths and misconceptions. The mobilizers liaise closely with the service provision teams to keep them informed about the level of demand in their respective areas and to avoid creating unmet demand. Mobilizers also keep provision teams abreast of the reasons men are stating for not wanting male circumcision, including myths that may be circulating in communities. The mobilizers are the eyes and ears of the program in the communities.

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6. VMMC Skills Training

VMMC Skills Training
Training for Community Mobilization Partners

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |

VMMC Counseling Training

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |

VMMC Clinical Skills Training

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |

Useful Tools	15 VMMC Standardized Job Descriptions 16 VMMC Counseling Training Package 17 Training Information Management System Forms
Useful International Guidance Documents	7 VMMC Video: Implementing Best Practices 8 WHO Manual for Male Circumcision under Local Anesthesia 9 VMMC Global Health e-Learning Course—Male Circumcision: Policy and Programming

Objective(s): To give VMMC service providers the required competencies to provide a full package of VMMC services, according to the established standards

Description: VMMC service providers need to be competent in the various skills required to provide VMMC services. The standard VMMC clinical training focuses on the competencies required to perform safe VMMC surgery under local anesthesia (see TOOL 16 AND GUIDANCE DOCUMENTS 7, 8, and 9). The clinical training package is based on the expectation that counselors possess a basic level of experience in counseling, and all clinical staff (i.e., doctors, nurses, and clinical officers) ideally have an appropriate background in surgery and/or surgical support. The MOH and/or Ministry of Defense must endorse clear training guidelines and competencies for VMMC staff prior to the start of VMMC service provision.

Any additional training (e.g., counseling, infection prevention, etc.) that may be required among any staff must be completed BEFORE the VMMC clinical skills training. Several countries have developed specific, dedicated VMMC counseling training courses, which provide more in-depth counseling skills.

Key considerations for training:
- When selecting staff to be trained, it is important that they are scheduled to begin performing VMMC immediately following training. This is critical to ensure that medical professionals retain the skills acquired in training and that training resources are used efficiently.
- Clinical staff on rotation may require refresher courses, if they rotate out of VMMC service delivery for an extended period.
- When possible, staff should be trained using instruments that are similar to those they will use on-site (i.e., if they will be using single-use disposable kits, they should use similar commodities for training). However, even if staff are likely to be using diathermy for hemostasis control, they should also be trained in suture ligation.
- In cases where VMMC services are established in a facility, it is best to establish a Memorandum of Understanding (MOU) with the host facility regarding training standards for VMMC service delivery to ensure that no untrained staff members perform VMMC services.

- All VMMC training must include the use of the emergency supplies in its curriculum. Every person working in a clinical role at the VMMC site should be adequately trained to use the supplies and equipment during an emergency.

- Concepts of voluntarism and informed consent should be explained to all staff trained in VMMC. It is a team responsibility to ensure voluntarism throughout all aspects of the program and to ensure that the proper informed consent procedure is conducted during clinical practice (see Section 14).

- It is important to keep an accurate record on file of the names of staff members who took the VMMC training and the date of the training. This information should be added to a database of trained providers and staff, and dates of refresher trainings should be maintained (see TOOL 17).

Suggested Staffing Roles for VMMC Programs

Program Management (Note: These are not site-level positions.) (see TOOL 15)

- Technical Advisor—Ensures the quality of the programs, including voluntarism and informed consent processes; generally one technical advisor per region works as part of the VMMC administrative team and provides oversight in the clinical area

- Data Manager—Oversees all data and data entry staff, oversees data M&E, and ensures data quality

- Supply Chain Management and Procurement Officer—Oversees central procurement and supply chains to all VMMC sites

- Administrative Assistant—Provides administrative support centrally

- Provincial/Regional Coordinator (one per province/region)—Ensures the highest quality service provision that adheres to international and national standards/protocols; provides overall strategic leadership and direction to ensure achievement of program objectives and targets

Clinical Staff (see TOOL 15)

- Site Manager—Coordinates site activities, manages commodities, ensures quality and logistics

- VMMC Provider—Removes foreskin, performs hemostasis and suturing (mattress sutures)

- Nurses—Flexible roles providing services and various roles including theater assistants, counselor, post-operative care, etc.

- Theater Assistant – "suture nurse"—Prepares client for surgery, ensures client is consented, assists with procedure, administers anesthesia, performs final stitching, and dresses wound

- Post-Operative Care Nurse—Performs pre-operative assessment counseling and history and physical, ensures that client is consented, provides post-operative care, schedules and conducts client education routine follow-up visits

- Hygienist/Cleaner/Infection Prevention Officer—Cleans and assists with cleaning surgical instrumentation, acts as runner

- Counselor—Provides VMMC counseling, HTC, client education

- Expert Clients—HIV-positive individuals who help other HIV-positive clients from the VMMC sites and the community understand, manage, and cope with chronic illness—including linking them to HIV care and treatment services and providing psychosocial support

- Community Health Workers—Assist with community demand generation and client post-operative follow-up

- Runner—Delivers supplies, provides varied assistance to staff, ensures equipment rooms are stocked, moves equipment and commodities to essential areas, and is an "extra pair of hands" to ensure smooth running operations

- Data Clerk—Maintains client records and enters relevant data

- Receptionist—Receives clients, assists with data management

- Driver (for mobile sites)—Transports personnel and provisions

## 7. Implementation of WHO Minimum Package of Services and Appropriate Linkages

Implementation of WHO Minimum Service Package

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |

Useful Tool	Appendix 4: Checklist on VMMC Counseling
Useful International Guidance Documents	8 WHO Manual for Male Circumcision under Local Anesthesia 10 Guidance on Provider-Initiated HIV Testing and Counseling (PITC) in Health Facilities 11 Guidelines for the Management of Sexually Transmitted Infections (STIs)

Objective(s): To ensure that services are being implemented according to the WHO-recommended package of services (see Figure 5)

Figure 5: Recommended Components of VMMC
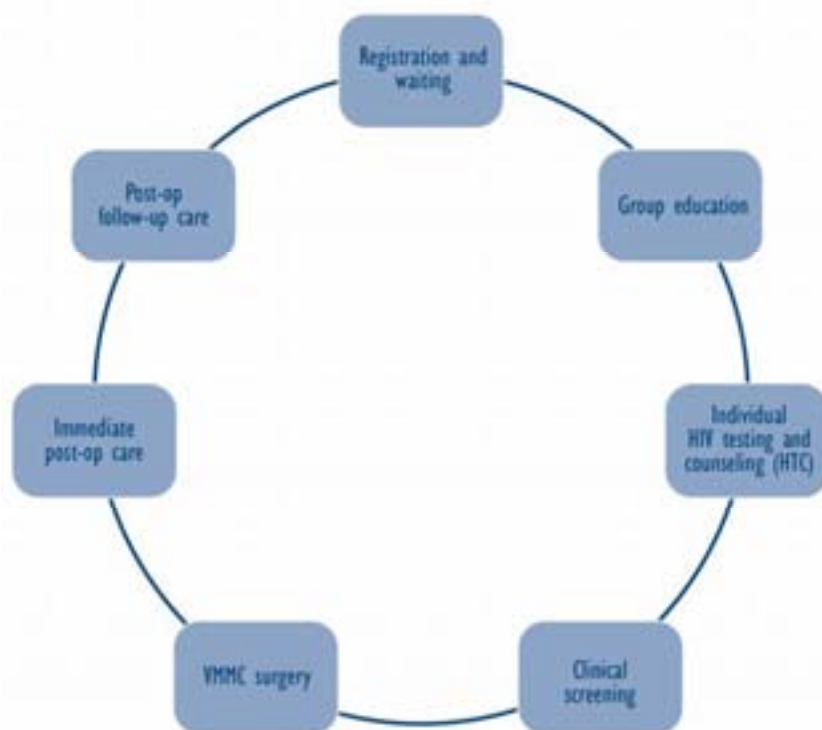
All VMMC programs should offer WHO's minimum package of services. WHO specifies that VMMC must be part of a comprehensive package of services, including:

- HTC (offer of) (see GUIDANCE DOCUMENT 10 and Appendix 4)
- Screening and treatment for STIs (see GUIDANCE DOCUMENT 11)
- Provision of male and female condoms, and promotion of their correct and consistent use
- Promotion of safer sex practices and provision of risk reduction counseling
- VMMC surgery (surgical removal of the foreskin) (see GUIDANCE DOCUMENT 8)

In addition to WHO's minimum package of services, PEPFAR also recommends including:

- Active linkages of HIV-positive clients from VMMC sites to HIV care and treatment programs

VMMC represents a rare and valuable opportunity to provide HIV testing and counseling (HTC) to men and, if necessary, to link them to care. When men seek VMMC services, it provides an ideal opportunity to address some aspects of sexual and reproductive health. Additionally, because many of the males accessing VMMC services are adolescents, VMMC provides a forum to educate young males about a variety of sexual health issues.

HTC in the facility and in the community can contribute to demand creation for VMMC services. It is important to capitalize on this opportunity by ensuring that HTC facilities are referring eligible clients to VMMC services.

As part of the WHO-recommended minimum package of services, PITC should be offered as part of the VMMC program (see GUIDANCE DOCUMENT 10). Implementers should adhere to WHO guidance on PITC, including the minimum standards of pre-test information, informed consent (see Section 14), post-test counseling based on serostatus, maintaining confidentiality, and use of point-of-care rapid HIV testing algorithms, as appropriate. In addition, it is important—as part of the WHO minimum package of services—to develop strong linkages to HIV care and treatment for clients who test HIV-positive. QA systems for HTC components should be in place to ensure high-quality HTC services in these settings, including systematic laboratory-based HTC results validation procedures.

Men who test HIV-positive as part of the VMMC program should be referred promptly to a care and treatment site for evaluation and appropriate antiretroviral therapy (ART), when clinically indicated. This may require that sites develop and implement novel mechanisms to facilitate and confirm successful linkage to care (e.g., escorting clients from the VMMC center to the ART center, or enabling staff to register clients for ART at the VMMC center). The limits of the protective benefits of VMMC should be explained to HIV-positive men and their partners, and if a client requests VMMC anyway (for reasons other than HIV prevention) and is healthy enough and is clinically fit (i.e., his CD4 count is above the treatment initiation threshold), VMMC should be made available to him.

If men test HIV-negative as part of the VMMC program services, they can be counseled and given specific information about how to protect themselves from HIV infection. Services for these men should include the provision of condoms and risk-reduction counseling.

VMMC should be recommended to all HIV-negative males who receive HTC services in any setting, especially those men who are at high risk of HIV acquisition from heterosexual sex (e.g., STI clinic clients and those in discordant partnerships). It is especially important for program staff to follow up actively with males whose circumcision procedure has been deferred because of an STI. It is crucial that VMMC programs develop routine systems to follow up with these males, who show evidence of having had unprotected sex, to ensure that they return to the VMMC facility for circumcision immediately following their STI treatment. VMMC programs should also give particular priority to HIV-negative males in HIV-discordant partnerships.

Case Study—Zimbabwe's Linkage to HIV Care and Treatment

In Zimbabwe's national program, HTC is offered routinely to all clients accessing VMMC services, and all male HTC clients who test negative are offered and referred to VMMC. Uptake of HTC has been nearly universal. All clients testing HIV-positive receive a point-of-care CD4 cell count offered at the HTC unit, and are referred with their results to public and private providers for HIV-related treatment and care services. VMMC providers have established direct links to referral centers. All referral information is entered into referral registers at the VMMC sites as well as at the referral centers. Over 90% of the referred clients could be followed up. These clients have been successfully accessing treatment, care, and support services to which they were referred by the VMMC sites.

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8. Support Launch of VMMC Services

Support Launch of VMMC Services

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |

Useful Tool	18	Quality Assessment Toolkit
Useful International Guidance Documents	2	Considerations for Implementing Models for Optimizing the Volume and Efficiency of Male Circumcision Services, 2010

Objective(s):

- To ensure a smooth startup of new VMMC services
- To reinforce the knowledge, attitudes, and skills of VMMC service provision acquired by new VMMC teams, and ensure that they have the necessary confidence, skills, and systems to provide quality services

Description: VMMC staff should begin providing VMMC services as soon as possible after training. By this point in the timeline for providing VMMC services, the VMMC site will have been prepared (see Section 3), and demand generation activities (see Section 5) will have been started. Demand generation should target a service launch date that occurs shortly after the completion of staff training—the shorter the gap between training and clinical practice, the higher the rate of education retention, and the greater the likelihood that the trained team will provide services that follow the recommended standards.

Despite the best efforts to prepare new VMMC sites, issues often arise that need to be addressed as service provision progresses. Even though the VMMC staff members will have been trained in their respective specialties (i.e., counseling, clinical, etc.), it is important to provide them with immediate on-site support and mentoring by a proficient VMMC provider, ideally by one of their trainers. This support will help them incorporate what they learned during training within their own service delivery setting. Designating an experienced, proficient VMMC provider as a mentor can help the team resolve any startup challenges. Mentors can provide support and advice to program managers and site managers in the areas of training, procurement, demand creation, client flow, and space designation. The use of mentors can ensure that, from the very beginning, the services are indeed being provided according to the accepted standards. During the launch of the site, the mentor can also orient the team to the VMMC standards for self-assessment, quality, and performance improvement (see TOOL 18). Most importantly, the mentor will ensure, from the beginning, the integration of efficiency models such as MODELS FOR OPTIMIZING VOLUME AND EFFICIENCY (MOVE) (GUIDANCE DOCUMENT 2).

> **Case Study—South Africa's Support for the Launch of VMMC Services**
>
> *South Africa's "Startup Approach"*
> South Africa utilizes "startup teams." These are specifically focused specialist VMMC support teams that assist sites to launch VMMC services. Government teams are often trained to offer VMMC services safely; however, additional follow-up support, through "Startup," ensures that experienced staff accompany these newly trained teams back to their sites and assist with smooth service delivery initiation. This "startup approach" includes assistance with site layout and planning, equipment (selection and installation), clinical supervision, management of AEs, and implementation of efficiency models.

9. Training VMMC Supervisors

Useful Tool	18	Quality Assessment Toolkit
Useful International Guidance Documents	8	WHO Manual for Male Circumcision under Local Anesthesia
	12	Supervising Health Care Services: Improving the Performance of People

Objective(s):   To ensure that VMMC supervisors have the supervision skills and specific technical knowledge about VMMC required for effective, supportive supervision

Description: For sustainability and integration of a VMMC program within the health system, it is envisioned that existing supervision systems will be strengthened and supported by key clinical and managerial site staff members who are responsible for their respective geographic locations. Supportive supervision is "a process that promotes quality at all levels of the health system by strengthening relationships within the system, focusing on the identification and resolution of problems, and helping to optimize the allocation of resources—promoting high standards, teamwork, and better two-way communication" [27]. The WHO MANUAL FOR MALE CIRCUMCISION UNDER LOCAL ANESTHESIA (see GUIDANCE DOCUMENT 8) includes tools used to assess providers before, during, and after service provision. In addition, a variety of Performance Improvement and QA materials have been developed that supervisors can use during their supportive supervision (see TOOL 18). Supervisors who are previously trained in supportive supervision need only the VMMC technical training, whereas supervisors who possess VMMC technical training may need only supportive supervision training (see GUIDANCE DOCUMENT 12).

> **Training VMMC Supervisors—Learning by Doing**
>
> VMMC training follows principles of competency-based training (CBT). CBT is different from traditional educational processes; it is learning by **doing**. VMMC training focuses on the specific knowledge, attitudes, and skills needed to provide the full package of services for clients. How the learner performs (e.g., demonstrated knowledge of the benefits of male circumcision and the role of partners; and most important, the ability to perform safe medical male circumcision) is emphasized rather than just what information the learner has acquired. Moreover, the VMMC training courses require that the clinical trainer facilitate and encourage learning rather than serve in the more traditional role of instructor or lecturer. Counseling and surgical skills competency are assessed objectively by evaluating overall performance. An essential component of VMMC training is **coaching** combined with supportive supervision, which uses positive feedback and problem-solving skills to encourage a positive learning climate. The coaching process ensures that the learners and providers receive **feedback** regarding performance: **Before practice**—supervisor/coach and learner/provider meet briefly before each practice session to review the skill/activity, including the steps/tasks, as described in the WHO MANUAL FOR MALE CIRCUMCISION UNDER LOCAL ANESTHESIA. **During practice**—the supervisor/coach observes, coaches, and provides feedback as the learner performs the steps/tasks outlined in the checklist. **After practice**—a feedback session should take place immediately after the visit/practice. Using the checklist, the supervisor/coach discusses the strengths of the provider's performance and also offers specific suggestions for improvement.

10. Adverse Event Management, Monitoring, and Reporting

Adverse Events Management, Monitoring, and Reporting

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |

Useful Tools	
Useful International Guidance Documents	8 WHO Manual for Male Circumcision under Local Anesthesia 13 PEPFAR Next Generation Indicators Reference Guide Appendix 5: Adverse Events Classification and Grading

Objective(s):
- To manage clinical adverse events related to VMMC surgery
- To ensure appropriate referrals for adverse events

Description: As PEPFAR programs reach greater numbers of males with VMMC, we can anticipate that complications or AEs will occur at an expected frequency/rate. Surgical procedures inherently involve risk; and although they are rare, severe adverse events—including death—do occur. Life-threatening complications will occur; and though unavoidable and infrequent, staff and sites must be prepared to manage them. Guidance on emergency equipment/supplies is provided by WHO, and readiness assessments are specifically recommended as part of quality assurance activities (see Section 13). US government agencies and implementing partners must assess all VMMC service sites to verify that the required emergency equipment/supplies are on site and readily available, haven't reached their date of expiration, and that staff members trained to use the emergency equipment/supplies are always available when VMMC services are being provided.

Although the rates of AEs related to VMMC surgery are typically low (approximately 2–4%), every program should plan on identifying and managing all possible intra-operative and post-operative AEs as quickly and efficiently as possible. AEs are expected as part of routine service delivery, and they do not (necessarily) indicate poor performance. Most AEs can be managed in a clinic setting, but an appropriate referral system should be in place in case of a more serious AE that requires transfer to a better equipped health facility (see GUIDANCE DOCUMENTS 8 and 13, and Appendix 5). A VMMC team working at a clinic or mobile site must make arrangements with the nearest referral center to ensure continuity of care for the client if an AE should arise. All AEs should be categorized as mild, moderate, or severe— based on specific criteria defined by the PEPFAR NEXT GENERATION INDICATORS REFERENCE GUIDE (see GUIDANCE DOCUMENT 13 and Appendix 5). Once AEs have been correctly diagnosed, either during or following surgery, they must be documented and tracked appropriately—either on a client record or on a separate AE form.

General AE management for VMMC programs (see GUIDANCE DOCUMENT 8):
- Equipped Sites and Trained Staff
  - Sites must be equipped to handle life-threatening emergencies, and trained staff should always be available while VMMCs are taking place.
- Client Education
  - Clients must be given sufficient education on the risks of VMMC surgery. Although AEs are rare, they are still possible—even in sterile environments with experienced staff. Clients need to be educated about the proper techniques for post-surgical care (e.g., washing practices, keeping

the bandage and wound site clean, removing the bandage). Site staff must remind the client of the importance of adhering to post-operative follow-up recommendations. These recommendations state that all clients, regardless of their healing status, should return to a clinical site within seven days following surgery. Clients must also be reminded that sexual abstinence is required for six weeks after VMMC. Clients must be informed of signs of complications and what should be done to manage them correctly. It is imperative that all clients know where emergency care can be found. All clients must also be provided with phone numbers they can call for emergency services, if complications arise.

- Post-operative Monitoring
  - It is important to observe and follow clinical signs (vital signs) of each client for at least 30 minutes after the VMMC, because this is the period when post-operative AEs most commonly become apparent.

- Follow-up Visits
  - Routine follow-up should occur within seven days of the initial VMMC to assess any AEs. Treatment of any mild AEs can happen during the follow-up appointments, or if necessary, during the appropriate referral.

- AE Rate Calculations
  - It is important to monitor and calculate the AE rates accurately in each service delivery site as well as monitor program-wide rates to ensure that they are not above expected AE rates. AE rates can be calculated by the number of clients with an AE(s)/total number of clients who return for follow-up. If a client does not return to a facility for follow-up care, then that client will not be counted in the AE rate denominator.

Adverse Event Monitoring and Management

Safety in a VMMC program is the highest priority, and it is vital that AEs be monitored and managed. Missed or mismanaged AEs pose substantial risks for VMMC service delivery programs. Correct and comparable (with other sites, programs, or countries) reporting is essential. Programs need to provide clear and detailed identification, classification, and treatment guidance for common AEs related to VMMC (see Appendix 5).

PEPFAR's Best Practices for Voluntary Medical Male Circumcision Site Operations

11. Routine Monitoring, Reporting, and Evaluation

Useful Tools	19 VMMC Client Record Form 20 VMMC Monthly Reporting Form 21 VMMC Client Register
Useful International Guidance Documents	13 PEPFAR Next Generation Indicators Reference Guide 14 A Guide to Indicators for Male Circumcision Programs in the Formal Health Care System, 2010 15 PEPFAR Guidance for Monitoring & Reporting VMMC Indicators

Objective(s):   To ensure the quality, safety, and progress of VMMC services by collecting, analyzing, and utilizing routine data from VMMC service provision

Description: VMMC programs should have the relevant data infrastructure in place so that routine data can be collected from the client records at each VMMC site (see TOOLS 19 and 21). Data can be collected either in paper or electronic format and then collated for routine reporting. Whenever feasible these data should be entered into a VMMC client database. Routine summary data should be compiled in daily, weekly, and monthly reports (see TOOL 20). These reports should be submitted to PEPFAR and the relevant government officials at the district level and upward, following health management information system (HMIS) reporting requirements (see GUIDANCE DOCUMENT 14). Additional information should be gathered during periodic supportive supervision visits. In order to maximize the usefulness of these data, proper analysis is needed to ensure that lessons learned from the data are put into practice at the site level. District, regional, and national levels should likewise have the capacity to collate, analyze, and utilize these data, and to ensure that the analyses are also communicated back to the sites.

Community mobilization data also need to be monitored and reported. Potential indicators include the number of people reached with messages that promote VMMC, clients booked (referrals) for VMMC, materials distributed, people reached with group education, people who underwent individual counseling, and people who underwent HTC.

Beginning in 2010, PEPFAR provided a list of VMMC indicators that funded programs are required to collect and report. Definitions to support the accurate collection of the indicators are provided. For detailed information on the PEPFAR VMMC indicators, please see the PEPFAR NEXT GENERATION INDICATORS REFERENCE GUIDE (GUIDANCE DOCUMENT 13). A new publication by PEPFAR called GUIDANCE FOR MONITORING & REPORTING VMMC INDICATORS (see GUIDANCE DOCUMENT 15) provides guidance on collecting, aggregating, and sharing of information about the VMMC services provided. Programs will be expected to report on indicators to PEPFAR, MOHs, and to other stakeholders; and when VMMC programs are rolled out, they will be expected to comply with PEPFAR reporting requirements. This guidance document is intended for those who are required to report indicators to PEPFAR (implementing partners and implementers). In addition, MOHs and other policymakers and stakeholders may find this guidance useful for understanding how to collect and use routine VMMC data and how to follow PEPFAR's monitoring and reporting guidelines.

Case Study—Tanzania's Development of Routine Monitoring and Evaluation Standards

Tanzania started a VMMC pilot in September 2009. The Ministry of Health and Social Welfare (MOHSW) brought together a Technical Working Group (TWG), and VMMC was designated to be under the National AIDS Control Program (NACP). The pilot, funded by PEPFAR, was carried out by three implementing partners. In December 2009, partners (facility in-charges, implementing partner staff) convened to discuss indicators and tools for VMMC. The output of that meeting was a draft set of tools and indicators, which all partners in the country agreed to use during the pilot period.

Following the first meeting, NACP took the lead in developing the national indicators. The partners and facility in-charges, who used the tools on a daily basis, took the lead in refining the tools and bringing suggestions back to NACP.

The second stakeholder meeting was convened by NACP in December 2010. In this two-day meeting, the draft indicators were refined (with input from international guidance documents from UNAIDS and PEPFAR), and the tools were thoroughly discussed. As an output of this meeting, a draft set of provisionally approved tools for VMMC was created, and it was re-stated that all partners supporting rollout of VMMC should use the standard set of tools.

By mid-2011, it became clear that management of VMMC data from multiple partners was no longer feasible using the previous methods. In response, a Web-access database was developed that will house monthly summary forms from facilities. In this system, the implementing partner supporting VMMC logs on and enters the monthly summary form data. All stakeholders (NACP, implementing partners, PEPFAR) have log-in access to view the data. Eventually, VMMC should be streamlined into a national HMIS data management system.

12. Special Studies

Useful Tools	
Useful International Guidance Document	16 [PEPFAR Country Operational Plan (COP) 2012 Technical Considerations](#)

Objective(s):   To ensure the quality of VMMC services by conducting periodic studies and/or evaluations to address specific issues not captured in routine M&E

Description: Routine data will help to monitor aspects of VMMC services; however, some components of quality care are not well-suited to monitoring through routine data collection (e.g., client perspectives on quality of services) and reporting. In addition, special aspects of VMMC services may warrant periodic, in-depth studies (e.g., changes in sexual risk behaviors, barriers to older men accessing services). Periodic or special studies can help the program improve the quality of all the services it offers (see GUIDANCE DOCUMENT 16).

Case Study—Tanzania's Qualitative Study on Attitudes and Beliefs Surrounding VMMC

Men's decisions about VMMC services are complex, influenced by culture and history, traditional beliefs, education, sexuality, gender relations, economic and marital status, exposure to urban culture, past experiences with health care services, and many more factors. A qualitative assessment was conducted in February 2011, in three districts of Iringa region, Tanzania, to inform the VMMC program implemented there by the Ministry of Health and Social Welfare (MOHSW), with support from PEPFAR.

This formative work aimed to improve the understanding of the attitudes and beliefs of adult men and women that may enhance or hinder uptake of VMMC in Iringa region, and to explore their views on service delivery. The VMMC program is still relatively new, and only 20% of recent VMMC clients were aged 20 and above. VMMC for HIV prevention will have the greatest immediate impact if men who are already sexually active (or soon will be) primarily access VMMC services. The need to promote VMMC in men over 20 years of age is supported by the fact that HIV prevalence is highest in men ages 35 to 39 in Tanzania [Tanzania HMIS 2009]. One hundred and forty-two men and women in the three districts participated in 13 focus group discussions and three participatory exercises, which included creation of timelines and seasonal calendars. The majority of the participants could accurately describe VMMC and its benefits, including biological benefits (e.g., cleanliness and disease prevention—including HIV/AIDS prevention), as well as perceived VMMC benefits (e.g., increased virility). In general, participants stated that, ideally, men should be circumcised before puberty. Some were proponents of infant VMMC, but most felt that VMMC is best performed during childhood. VMMC during adulthood (defined by participants as married men, and those over the age of 24) was described as something unusual and perhaps embarrassing. VMMC was seen as something associated with modernity and urban environments, as well as secondary education, which usually involves the mixing of children from different ethnic groups—often in a boarding situation.

13. Internal and External Quality Assurance (EQA)

Internal and External Quality Assurance

Internal Quality Assurance

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |

External Quality Assurance

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |

Useful Tools	18 Quality Assessment Toolkit 18.2 VMMC Self Assessment Tool
Useful International Guidance Documents	17 External Quality Assurance (EQA) Tools developed by PEPFAR 18 Male Circumcision Quality Assurance: A Guide to Enhancing the Safety and Quality of Services

Objective (s):   To ensure that the VMMC services provided in the site meet the global standard for safety and efficiency

Description: Routine self-assessments of quality should be a continuous and ongoing activity to ensure that any difficulties with quality are identified quickly and remedied (see TOOL 18, 18.2). Country programs should reinforce the need for VMMC sites to conduct routine self-assessments of quality on a given schedule and implement a continuous quality improvement for VMMC services, as well as facilitate external quality assurance (EQA) assessments (see GUIDANCE DOCUMENT 17). EQA assessments by WHO, national departments/MOHs, or donors, along with international institutions, provide an opportunity for sites to improve their performance further and to identify areas needing support. Routine self-assessments should occur at least quarterly, and EQA exercises at least annually. Both activities should occur more frequently if serious issues are identified. Routine self-assessment can and should be integrated within any existing quality improvement strategies a given country put in place. The VMMC self-assessment tool (18.2) should be revised and adapted annually to meet the needs of the program.

The goals of a VMMC EQA assessment are to ensure that all the sites funded by PEPFAR are providing VMMC for HIV prevention according to best clinical practices and guided by PEPFAR's standards; and to provide information to national and local governments and individual VMMC sites regarding the quality of the services being delivered.

The objectives of VMMC EQA assessment visits are to:
- Monitor PEPFAR-funded VMMC service delivery programs by conducting QA assessments of implementing partners' service sites in resource-limited settings
- Assure that all PEPFAR-funded VMMC service provision meets appropriate standards and best clinical practices
- Provide technical assistance and support for program improvement where needed
- Build/strengthen the capacity of respective MOHs to conduct VMMC quality assurance (QA)

An EQA assessment typically takes three to four hours per site and includes direct observation of facility procedures and activities, including counseling sessions and actual VMMC surgeries, staff interviews, review of material resource inventories (e.g., supplies, medications, written materials), and a review of

client registers and records. Findings from the EQA assessments are summarized by general and site-specific reports (see GUIDANCE DOCUMENT 17). The general report helps national task forces and MOHs to identify their programs' strengths and challenges. Site-specific reports help national programs and local facilities craft specific interventions to fill gaps. The assessments yield immediate and tangible benefits including increased partner and governmental buy-in, rapid identification of barriers to service efficiency and demand creation, and practical feedback on infection control and waste management. The EQA assessments complement existing normative guidance and routine monitoring, and can easily be adapted to differing local and health contexts.

Case Study—Kenya's and Zambia's External Quality Assurance (EQA) for VMMC Programs

Kenya's first EQA assessment occurred in April 2009. During this assessment, a multi-disciplinary team visited 17 VMMC sites. The overall quality of surgical care was excellent, though several issues affecting program quality and productivity were identified: insufficient clinical staff to conduct an adequate number of procedures, variable rates of HTC uptake, occasional stock-outs of supplies, and sub-optimal documentation in client medical records. Specific recommendations made by the EQA team led to substantial improvements in performance, as documented by the follow-up visits conducted in November 2009. At the second assessment, more staff had been dedicated to providing VMMC services, medical record documentation had improved, and better client flow and organization was evident.

As in Kenya, Zambia's first EQA visit in February 2011 confirmed the strong commitment and clinical expertise of MOH and PEPFAR's other implementing partners. The assessments also identified issues related to productivity and efficiency at some sites. Older men were generally not accessing services, and implementing partners were using different client record forms to capture clinical information. Following the feedback from that EQA visit, Zambia's MOH has moved toward standardized national clinical recording and reporting tools for all partners and has prioritized dedicating more staff to VMMC full time. These efforts have contributed to improvements in the overall quality of Zambia's VMMC program.

14. Voluntarism, Informed Consent, and Reimbursement

Voluntarism, Informed Consent, and Reimbursement

1	2	3	4	5	6	7	8	9	10	11	12

Useful Tools	22 Sample VMMC Consent Form
Useful International Guidance Documents	16 PEPFAR Country Operational Plan (COP) 2012 Technical Considerations 19 UNAIDS Safe, Voluntary, Informed Male Circumcision and Comprehensive HIV Prevention Programming: Guidance for Decision-Makers on Human Rights, Ethical and Legal Considerations

Objective (s): To ensure that male circumcision services are carried out safely, under conditions of informed consent, and without coercion

Informed consent is a key element for any VMMC program. Informed consent is the voluntary agreement of an individual—or his authorized representative who has the legal capacity to give consent—to undergo a specific medical procedure. All VMMC site staff must be trained in the principles of informed consent and in the appropriate ways to obtain it (see GUIDANCE DOCUMENTS 16 and 19). Adult males opting for VMMC have the right to receive full information on the benefits and risks of the procedure. Only adult male clients who have the appropriate decision-making capacity and legal status are able to give their informed consent. The informed consent process should be conducted in a language that is understood by the VMMC client and his parent or guardian, as necessary.

A child (as defined by national law) generally lacks the legal status required to provide independent, informed consent. However, children and adolescents have the right to participate in decisions affecting their health, and therefore can provide assent for the surgical procedure. Those too young to understand the male circumcision procedure and provide assent should have the procedure deferred. Assent is the expression of willingness to undergo a procedure by a person who is by definition (according to his evolving capacity and national laws) too young to give informed consent, but who is old enough to understand the procedure. If assent is given, informed consent must also still be obtained from the subject's parents or guardians. Parents or guardians who are responsible for providing consent should be given sufficient information regarding the benefits and risks of the procedure to determine what is in the best interest of the minor. In countries with laws that allow minors to give independent informed consent, providers must ensure that the client's personal health history information is not disclosed to the parents without the minor's consent.

Elements of Informed Consent for VMMC Surgery

Obtaining informed consent is a process, not just a signed document. It is important that the elements below are covered in the informed consent process.

Informed consent should include the following elements:
- Purpose of the procedure
- Description of the procedure
- Explanation that male circumcision is permanent
- Potential risks and benefits
- Expected time of the procedure
- Explanation that it is a voluntary procedure
- Confirmation that the client understands the key information
- Time for questions and answers

All clients (or parents/guardians in the case of a minor) must give informed consent before a male circumcision is performed.

Consider the following items when developing informed consent procedures:
- Literacy level of clients (and parents/guardians)
- Awareness and acceptance of the individual's rights to make an informed decision
- Societal norms and pressures
- Service providers' attitudes toward the client's rights and ability to make his own decision
- Staff time available to allow time for questions and answers
- Confidentiality
- National regulations/policies
- Donor's policies

Note: Informed consent must be documented with a patient's or parent's/guardian's signature indicating that the elements of informed consent (first list of bullets above) were covered and that the signer consents to the procedure (see TOOL 22). It is also important to comply with national guidelines and laws on how to document informed consent. Generally, signed consent forms are kept with the patient charts; it is important to ensure that the national protocols—including where to file the signed consents, and how long they need to be kept—are followed.

Paying clients (in money or other material goods) to undertake VMMC is not permitted in any circumstances. Any reimbursement of money or goods given to clients must be used cautiously, to avoid coercion, including the appearance of coercion.

Reimbursement for Procedure-Related Expenses—Depending on the need for overcoming barriers for VMMC uptake, countries may consider offering reimbursement for travel expenses typically incurred by clients as a result of undergoing VMMC. Such reimbursements should be set based on reasonable transport costs within the specific geographic and population context and must be monitored closely to avoid inappropriate or unethical practices, including coercion. Wage reimbursements should NOT be introduced in PEPFAR-supported programs unless there is strong evidence that the strategy addresses a well-documented barrier. Programs that have documented loss of wages as a barrier to VMMC uptake must contact the MOH of their respective countries and PEPFAR with a proposal on how they would set rates, manage, and administer such payments to ensure that they would not represent a coercive incentive to potential clients and not distort any existing national schemes.

Benefits/Gifts Provided—Peer mobilizers are often very effective in increasing demand for VMMC. Programs that use peer mobilizers must develop systems to monitor the quality of their activities to assure that recruited clients are well informed about VMMC and have not been pressured or coerced to

undergo the procedure (e.g., mobilizers should be monitored to ensure that they do not give t-shirts only to VMMC acceptors instead of to all). Community mobilizers may be rewarded for exceptional performance. Programs electing to give rewards to highly successful mobilizers must take steps to prevent the coercion of clients by mobilizers who may otherwise be financially motivated to pressure individuals. Mobilizers should never be compensated on a one-to-one basis, meaning that an individual mobilizer should not receive money for each client who undergoes VMMC. For example, it is better to reward a team of mobilizers that exceeds expectations, so that any reward is based upon collective (vs. individual) success. The above approach limits the likelihood of coercion by separating any immediacy of reward resulting for an individual mobilizer referring a particular client. Mechanisms that may even further distance perceived or actual rewards on a per-client/per-mobilizer basis are encouraged.

Staff Compensation—Clinicians who work overtime to provide VMMC services may be compensated for their time at a scale consistent with national standards. However, clinicians should not be compensated on a per-procedure basis, to avoid actual or perceived motivation for clinicians to coerce clients to undergo the procedure.

Program Targets—The use of targets for individual service providers, or mobilizers should be avoided because it can lead to possible coercive practices. For the site, estimated targets should be used for planning and/or evaluation purposes only (e.g., order estimates for commodities, staffing levels, number of outreach sites needed, site and staffing efficiency).

To ensure voluntarism and informed consent, programs should not only provide appropriate informed consent for clients, but they should also:

- Develop indicators and standards within the regular M&E practices to monitor consent delivery and guarantee client comprehension, evaluate for coercive activities, and review reimbursement procedures (see Section 11)
- Avoid practices outlined above that can be perceived to be coercive
- Give special consideration to the needs of children and/or adolescents
- Avoid numerical program objectives or staff/site performance targets or quotas

15. Health Care Waste Management

Health Care Waste Management

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |

Useful Tools	23	Supply Chain Management System (SCMS). Male Circumcision Health Care Waste Management Toolkit: SCMS 2012
Useful International Guidance Documents	20	Management of Solid Health Care Waste at Primary Health Care Centers: A Decision-Making Guide

Objective(s): To ensure that health care risk waste is properly managed in order to protect health workers, the community, and/or the environment

Description: Waste produced during VMMC activities carries a high risk of infection and injury for health care professionals and patients, if not managed properly. To avoid serious public health consequences and substantial environmental impact, it is essential to develop safe and reliable methods for handling and treating health care risk waste (HCRW) (see TOOL 23).

Health care waste management (HCWM) spans a number of different stages from generation, to treatment, to disposal of waste (HCWM cycle or cradle-to-grave cycle). To regulate the many steps within the cycle, service providers must have clear standard operating procedures on the segregation, handling, storage, transport, treatment, and disposal of waste. The easiest way to establish proper HCWM is to draft a waste management plan based upon local norms, standards, and/or guidelines—or, in their absence, refer to WHO guidance materials (see GUIDANCE DOCUMENT 19). This plan will address the HCWM cycle by carefully implementing necessary measures and allocating resources through cost-effective solutions. To ensure proper management, a successful HCWM plan should:

- Clearly define the point of generation within the service site(s) (e.g., blood-drawing area, operating theater, HTC areas, and recovery area)
- Propose HCWM product requirements/specifications
- Develop procedures and job aids for the identification, segregation, storage, transport, treatment, and disposal of health care waste
- Set standard requirements for clinical staff safety and training (e.g., training schedule, personal protective equipment, cleaning, and personal hygiene)
- Develop a monitoring and incident reporting system
- Propose environmentally sound treatment and disposal methods
- Define responsibilities of clinical staff, administration, regional and local governments

Countries are required to establish a proper health care waste management system that addresses segregation, storage, transport, treatment, and disposal of all relevant health care waste categories. When designing a waste management system, it is essential to assess local infrastructure upfront, to determine which accepted option will emerge as the most practical. The options for the disposal of metal instruments include the burial of instruments in a secure sharps pits/concrete vault, transporting the instruments to a recycling/smelting facility, or specialized encapsulation.

To ensure that short-term and long-term VMMC service sites are fully prepared prior to the launch of services, HCWM requirements and specifications must be independently assessed to identify waste management practices, procedures, and risks at the national, regional, and service site levels. This

assessment must be incorporated into the VMMC facility assessment. In addition, service sites must ensure that all required HCWM commodities are clearly specified during the planning stage and allow for adequate lead times.

Case Study—Health Care Waste Management (HCWM)

To help reduce HIV transmission, the Government of the Kingdom of Swaziland established a campaign to perform over 80,000 adult VMMCs. The existing HCWM infrastructure could not support the additional waste generated. Therefore, the national government requested PEPFAR's assistance to strengthen their systems. The Supply Chain Management System (SCMS) was tasked to work with the national government to assess and improve the existing HCWM infrastructure to manage the campaign's health care risk waste (HCRW) properly.

Systems strengthening efforts were coordinated with the MOH and Swaziland Environmental Authority through each stage of development and implementation of the system. The following key activities were included:
- Guidelines were developed that outlined standard operating procedures (SOPs) for handling, storing, treating, and disposing of health care waste, as well as personnel training requirements.
- A chain of responsibility was created so that personnel are accountable for every step in the process, and the process is managed accordingly.
- Secure storage areas were developed that are accessible only to authorized personnel. These storage areas are protected from the weather and/or other environmental factors.
- A waste collection and delivery system was established to move infectious waste from the VMMC service sites to regional hospitals for treatment and final disposal.
- A monitoring tool was developed that empowers the MOH to conduct regular program monitoring. This monitoring tool ensures that practices are properly maintained so that risk and disease are minimized.
- The required waste disposal commodities, hazardous waste liners, bins, and personal protective equipment were procured.
- Training curricula and materials were developed that address the critical requirements for the program so that the safety of staff and safe handling of infectious waste can be ensured.

The overall outcome was the establishment of a waste management program with national applicability that begins at the point of generation and extends to disposal.

Through coordinated infrastructure improvements (e.g., incinerator refurbishment and installation; strengthened supply chains; development and implementation of SOPs, training curricula, and monitoring; and establishment of public-private partnerships for services such as waste transport), a HCWM system was developed. This system has been replicated and implemented in other service sites and health facilities.

PEPFAR's Best Practices for Voluntary Medical Male Circumcision Site Operations

APPENDIX 1: KEY PHASES IN ESTABLISHING NEW VMMC SERVICES

This appendix provides a summary of the key points in all of the sections of this *Best Practices* document, and relevant resources for each of the sections.

Phases/Activities	Tools/Guidance Documents and Figures/Appendices
1. Service Site Selection ▪ Work with MOH and local authorities to identify appropriate locations ▪ Determine site options (fixed, mobile, outreach), type of service delivery, and staffing options	Tool 1: VMMC Site Selection Criteria Tool Tool 2: VMMC Site Readiness and Preparation Tool Guidance Document 1: Operational Guidance for Scaling Up Male Circumcision Services for HIV Prevention
2. Service Site Planning ▪ Conduct a thorough site assessment, including a site management orientation (with appropriate authorities and technical implementing partners) ▪ Conduct a thorough orientation for site staff on VMMC for HIV prevention ▪ Develop a detailed site preparation action plan	Tool 2: VMMC Site Readiness and Preparation Tool Tool 3: VMMC Site Action Plan Tool 4: VMMC Site Assessment Tool Tool 5: Community Asset Mapping Guidance Document 2: Considerations for Implementing Models for Optimizing the Volume and Efficiency of Male Circumcision Services, 2010 Guidance Document 3: Supply Chain Management System (SCMS) E-catalog including all Male Circumcision Kit Options Guidance Document 4: Male Circumcision Waste Management Plan
3. Service Site Preparation Prepare the site so that it is ready to ▪ Provide VMMC services that meet the minimum standards ▪ Launch services when staff training is completed ▪ Ensure efficient client flow	Appendix 2: VMMC Service Site Preparation Planning Template Figure 4: VMMC Client Flow Diagram Guidance Document 3: Supply Chain Management System (SCMS) E-catalog including all Male Circumcision Kit Options
4. Procurement of Commodities ▪ Conduct a forecasting and supply planning exercise ▪ Conduct procurement and logistics planning ▪ Make decisions about disposable versus reusable VMMC kits	Tool 6: SCMS Intro Letter 2012 Tool 7: PFSCM Client Toolkit Tool 8: Automated Directives System (ADS) 312 USAID Pharmaceutical Approval Process Tool 9: Quantification, Forecasting, and Monitoring Basic Tool for VMMC Tool 10: Male Circumcision Model—Costing Tool for Public Hospitals Guidance Document 3: Supply Chain Management System (SCMS) E-catalog including all Male Circumcision Kit Options Guidance Document 5: PEPFAR Male Circumcision Partners' Meeting: Commodities and Improved Coordination of Male Circumcision for HIV Prevention
5. Creating Demand ▪ Provide the community with accurate and complete information about VMMC ▪ Build demand for VMMC ▪ Provide all information necessary for informed consent among eligible men ▪ Ensure that supply of services is appropriate to meet demand for services	Tool 11: Communication Strategy for Voluntary Medical Male Circumcision in Kenya Appendix 3: Phases of VMMC-Related Communication Tool 12: Communication Materials Adaptation Guide Tool 13: A Guide to Working with the Media to Promote VMMC in Kenya Tool 14: VMMC Video Discussion Guide Guidance Document 6: VMMC Demand Creation Toolkit

Phases/Activities	Tools/Guidance Documents and Figures/Appendices
6. VMMC Skills Training ▪ Ensure that VMMC service providers have the required competencies to provide a full package of services, according to established standards	Tool 15: VMMC Standardized Job Descriptions Tool 16: VMMC Counseling Training Package Tool 17: Training Information Management System Forms Guidance Document 7: VMMC Video: Implementing Best Practices Guidance Document 8: WHO Manual for Male Circumcision under Local Anesthesia Guidance Document 9: VMMC Global Health e-Learning Course—Male Circumcision: Policy and Programming
7. Implementation of WHO Minimum Package of Services and Appropriate Linkages Ensure that services are being implemented according to the WHO-recommended package of services and PEPFAR recommendations ▪ Offer HIV testing and counseling ▪ Screen for and treat STIs ▪ Provide male and female condoms and promote correct and consistent use ▪ Promote safer sex practices and provide risk reduction counseling ▪ Provide VMMC surgery ▪ Provide active linkages of HIV-positive clients to care and treatment	Appendix 4: Checklist on VMMC Counseling Guidance Document 10: Guidance on Provider-Initiated HIV Testing and Counseling in Health Facilities Guidance Document 11: Guidelines for the Management of Sexually Transmitted Infections (STIs) Guidance Document 8: WHO Manual for Male Circumcision under Local Anesthesia
8. Support Launch of VMMC Services ▪ Ensure smooth startup of new VMMC services ▪ Reinforce VMMC service provider knowledge, attitudes, and skills ▪ Ensure that providers have the necessary confidence, skills, and systems to provide quality services	Tool 18: Quality Assessment Toolkit Guidance Document 2: Considerations for Implementing Models for Optimizing the Volume and Efficiency of Male Circumcision Services, 2010
9. Training VMMC Supervisors ▪ Ensure that VMMC supervisors have the supervision skills and specific technical knowledge about VMMC required for effective, supportive supervision ▪ Ensure that VMMC supervisors are able to assess providers before, during, and after service provision ▪ Ensure that VMMC supervisors are able to use Performance Improvement and Quality Assurance materials during supportive supervision	Tool 18: Quality Assessment Toolkit Guidance Document 8: WHO Manual for Male Circumcision under Local Anesthesia Guidance Document 12: Supervising Health Care Services: Improving the Performance of People
10. Adverse Events Management, Monitoring, and Reporting ▪ Manage clinically adverse events related to VMMC surgery ▪ Ensure that appropriate referrals are made for adverse events	Guidance Document 8: WHO Manual for Male Circumcision under Local Anesthesia Guidance Document 13: PEPFAR Next Generation Indicators Reference Guide Appendix 5: Adverse Events Classification and Grading

PEPFAR's Best Practices for Voluntary Medical Male Circumcision Site Operations

Phases/Activities	Tools/Guidance Documents and Figures/Appendices
11. Routine Monitoring, Reporting, and Evaluation ▪ Collect, analyze, and utilize routine data from VMMC service provision to ensure quality, safety, and progress ▪ Ensure that VMMC programs have the relevant data infrastructure in place so that routine data can be collected from client records at each VMMC site ▪ Monitor and report community mobilization data	Tool 19: VMMC Client Record Form Tool 20: VMMC Monthly Reporting Form Tool 21: VMMC Client Register Guidance Document 13: PEPFAR Next Generation Indicators Reference Guide Guidance Document 14: A Guide to Indicators for Male Circumcision Programs in the Formal Health Care System, 2010 Guidance Document 15: PEPFAR Guidance for Monitoring & Reporting VMMC Indicators
12. Special Studies Conduct periodic studies and/or evaluations to address specific issues not addressed in routine M&E, for example: ▪ Client perspectives on quality of services ▪ Changes in sexual risk behaviors ▪ Barriers to older men accessing services	Guidance Document 16: PEPFAR Country Operational Plan (COP) 2012 Technical Considerations
13. Internal and External Quality Assurance Ensure that VMMC services provided at the site meet the global standard for safety and efficiency by conducting routine self-assessments at least quarterly, EQA assessments at least annually; conduct both activities more frequently if serious issues are identified ▪ Implement ongoing routine self-assessments ▪ Facilitate periodic external assessments (e.g., EQA assessments by WHO, national departments/MOHs, donors, international institutions) ▪ Summarize and report EQA assessment findings	Tool 18: Quality Assessment Toolkit Guidance Document 17: External Quality Assurance (EQA) Tools developed by PEPFAR Guidance Document 18: Male Circumcision Quality Assurance: A Guide to Enhancing the Safety and Quality of Services

Phases/Activities	Tools/Guidance Documents and Figures/Appendices
14. Voluntarism, Informed Consent, and Reimbursement Ensure that VMMC services are carried out voluntarily, safely, under conditions of informed consent, and without coercion - Ensure that all VMMC site staff understand the principles of informed consent and appropriate ways to obtain it - Develop indicators and standards within regular M&E practices to monitor consent delivery and guarantee client comprehension, evaluate for coercive activities, and review reimbursement procedures - Review with VMMC site staff and mobilizers standards of practice regarding reimbursement, benefits or gifts, staff compensation, program targets, numerical objectives, or quotas so that staff/mobilizers can avoid practices that can be perceived to be coercive - Give special consideration to the needs of children and/or adolescents	Tool 22: Sample VMMC Consent Form Guidance Document 16: PEPFAR Country Operational Plan (COP) 2012 Technical Considerations Guidance Document 19: UNAIDS Safe, Voluntary, Informed Male Circumcision and Comprehensive HIV Prevention Programming: Guidance for Decision-Makers on Human Rights, Ethical and Legal Considerations
15. Health Care Waste Management Protect health workers, the community, and/or the environment by ensuring that health care risk waste is managed properly	Tool 23: Supply Chain Management System (SCMS). Male Circumcision Health Care Waste Management Toolkit: SCMS 2012 Guidance Document 20: Management of Solid Health Care Waste at Primary Health Care Centers: A Decision-Making Guide

APPENDIX 2: VMMC SERVICE SITE PREPARATION PLANNING TEMPLATE

This tool can be used as a task log to plan activities, determine who is responsible for completion of the task, as well as track the progress. This tool can help program managers ensure that all tasks are on track to be completed prior to the launch of services.

Site Setup Activities	When (Start Date [SD]) Minimum	Needs	Responsible	Remarks
Site selection	4 weeks before launch of services	Site selection criteria		
Site layout—Develop site setup guide including secure areas for supply storage	12 working days before SD	Site map		
Supplies to new site	7 working days before SD	Supply checklist Receiving form		
Site setup—setting up rooms, tents, etc.	5 working days before SD	Site setup guide, including tent or marquee setup		
Internal assessment	Immediately after site setup	Site management and team		
Site readiness assessment	3 days before SD	Site readiness tool		
Whole site orientation	First day of service	Orientation package, objectives		

APPENDIX 3: PHASES OF VMMC-RELATED COMMUNICATION

Phase I: Demand Creation—Step I: Advocacy	
Objectives:	(1) Create an enabling environment by increasing political and social commitment toward leading VMMC service delivery efforts, and (2) Mobilize key financial and human resources
Primary Audiences:	MOH, district departments of health, other relevant ministries, site management teams, feeder clinics, and other implementation partners
Secondary Audiences:	Community leaders (e.g., mayors, councilors, traditional leaders, village elders); educational, business, faith, and community group leaders; local media
Key Messages:	Health benefits of VMMC, information about the VMMC procedure, facts about introduction of services
Channels/Activities:	Bilateral discussions, stakeholder meetings, group training
Suggested IEC Tools:	Targeted fact sheets and/or brochures
Phase I: Demand Creation—Step II: Social Mobilization	
Objectives:	(1) Mobilize the community to examine attitudes and social norms relating to VMMC, HIV prevention, and gender, (2) Accept VMMC as a healthy social norm relevant to manhood and responsible sexual behavior, and (3) Begin to seek out VMMC as an HIV prevention intervention
Primary Audiences:	Community members (schools and teachers; workers; church members; men's, women's, and youth groups; etc.)
Key Messages:	Health benefits of VMMC, partially protective nature of VMMC, role of males in accepting VMMC as one aspect of combination HIV prevention, gender issues related to VMMC
Channels/Activities:	Small group activities, community theater, panels/debates, community media (e.g., call-in radio shows, local media coverage)
Suggested IEC Tools:	Facilitation guides, flip charts, theater/radio scripts, press releases, targeted fact sheets and/or brochures, t-shirts for interpersonal communication (IPC) agents

Phase I: Demand Creation—Step III: Focused Demand Creation	
Objectives:	Encourage communities and individuals to take an active role in demanding and seeking out VMMC services: (1) Motivate uncircumcised men to go for VMMC, and (2) Motivate partners and caregivers to encourage men to go for VMMC
Primary Audiences:	Potential male clients of VMMC—target specific age groups, as locally appropriate (e.g., younger men ≤20 years, middle-aged men 21–40 years, and older men >40 years)
Secondary Audiences:	Couples, partners (wives, girlfriends, lovers), and caregivers (mothers and grandmothers), guardians (and older brothers and sisters of orphans and vulnerable children [OVC] who are their guardians)
Key Messages:	- VMMC is different from traditional male circumcision. - VMMC reduces the risk of HIV infection by approximately 60%, providing only partial protection. - <u>VMMC provides reduction of ulcerative STIs among men and cervical cancer among women.</u> - VMMC reduces a man's risk of acquiring HIV through heterosexual intercourse by approximately 60%. VMMC indirectly protects the man's female sexual partner from HIV because circumcision reduces his HIV risk—and an HIV-negative man cannot infect a female sexual partner. Therefore, his female sexual partner(s)' risk of HIV will be decreased. However, for an HIV-positive man, VMMC will not reduce his risk of transmitting HIV to his female sexual partner(s). Correct and consistent condom use is critical for preventing HIV. - Circumcised men still need to practice other HIV risk reduction strategies (e.g., reducing their number of sexual partners). - Visit this clinic to proceed with VMMC.
Channels/Activities:	Peer-to-peer IPC activities, large events, road shows, broadcast media (local TV/radio), outdoor (billboards), print (magazines, newspapers)
Suggested IEC Tools:	Facilitation guides, flip charts, banners, posters, flyers, referral/appointment cards, targeted fact sheets and/or brochures, t-shirts for IPC agents

Phase II: Service Delivery—Step I: Initial VMMC Education and Counseling	
Objectives:	Inform potential clients, as well as partners, guardians, and family members about the facts of VMMC and combination HIV prevention
Primary Audiences:	Potential male clients of VMMC—target specific age groups, as locally appropriate (e.g., younger men ≤20 years, middle-aged men 21–40 years, and older men >40 years)
Secondary Audiences:	Couples, partners (wives, girlfriends, lovers), and caregivers (mothers and grandmothers), guardians, and older brothers and sisters who are guardians of OVC
Key Messages:	- VMMC is different from traditional male circumcision. - VMMC reduces the risk of HIV infection by approximately 60%, providing only partial protection, and condoms must be used consistently and correctly after VMMC. - VMMC reduces a man's risk of acquiring HIV through heterosexual intercourse by approximately 60%. VMMC indirectly protects the man's female sexual partner from HIV because circumcision reduces his HIV risk—and an HIV-negative man cannot infect a female sexual partner. Therefore, his female sexual partner(s)' risk of HIV will be decreased. However, for an HIV-positive man, VMMC will not reduce his risk of transmitting HIV to his female sexual partner(s). - Promotion of safer sex practices - Delivery of risk reduction information - Correct and consistent condom use is critical for preventing HIV. - Reduction of multiple and concurrent partners will reduce risk of HIV infection. - Follow-up visits on Days 2 and 7 are critical to ensure proper wound care and healing. - Post-operative care during the VMMC recovery period requires hygienic wound care and six weeks of abstinence from sexual intercourse and masturbation. - HIV and STI testing are part of the VMMC process.
Suggested IEC Tool:	Targeted brochures for each audience that reinforce key messaging

Phase II: Service Delivery—Step II: Pre-Test HIV Testing and Counseling (HTC)	
Objectives:	Deliver risk reduction information and encourage HIV testing
Primary Audience:	Male clients of VMMC
Secondary Audiences:	Couples, partners, and caregivers (for on-site HTC or active referral)
Key Messages for All Potential HTC Clients:	▪ HIV test results are confidential. ▪ Modes of HIV transmission in this community are… ▪ Methods of HIV prevention are… ▪ The process of HIV testing is... ▪ Partner testing is very important and sexual partners should be referred by the HTC client, including for possible future couples counseling and HIV testing.
Key Messages for Consenting Clients:	▪ Prepare consenting clients mentally for HIV results.
Key Messages for Clients Who Do Not Consent:	▪ You should not hesitate to test for HIV. ▪ There are benefits to knowing your status. ▪ You are encouraged to seek testing in the future. ▪ You can visit the following locations for HIV testing in the future.
Suggested IEC Tool:	▪ Referral card to provide active linkage to off-site HTC, if testing is refused
Phase II: Service Delivery—Step III: Individual Post-Test HIV Testing and Counseling (HTC)	
Objectives:	Communicate HIV test results and offer support, where appropriate
Primary Audience:	Male clients of VMMC
Secondary Audiences:	Couples, partners, and caregivers (for on-site HTC or active referral)
Key Messages: HIV-Negative Clients:	▪ An HIV-negative test indicates that no HIV antibodies are in the blood. ▪ When clients are given their negative test results, they should be screened for previous or ongoing risk for HIV infection. Providers should determine whether these clients are injection drug users, sex workers, or men who have sex with men; have high-risk or known HIV-positive partners; or have clinical indications for re-testing such as newly acquired sexually transmitted infections (STIs) that would necessitate another test in four weeks. Providers should ask HIV-negative clients the following questions: Can you identify a specific incident of HIV exposure in the three months prior to your test (i.e., occupational exposure, unprotected sex with a known HIV-positive person, or sharing injecting equipment with a known HIV-positive person)? Providers should remind these clients that VMMC is only partially protective against HIV; so, it is important to practice other HIV prevention strategies in order to stay negative. ▪ Promotion of safer sex practices
Key Messages: HIV-Positive Clients	▪ HIV can be treated with antiretroviral therapy (ART). ▪ You should disclose your status to your partner(s) unless doing so will create a risk (e.g., undergoing gender-based violence after disclosure). ▪ Encourage your partner(s)/family members to be tested. ▪ You need to obtain your CD4 count to be able to access ART and/or learn about other care and treatment support available to you. ▪ You may still be circumcised if your CD4 count is greater than the treatment initiation threshold. ▪ VMMC will not reduce the risk of transmitting HIV to your partner(s). ▪ Your healing process may be longer; so, proper wound care is important. ▪ Use condoms consistently and correctly to prevent HIV transmission. ▪ Use this referral for active linkage to HIV care and treatment.
Suggested IEC Tool:	▪ Referral cards to provide active linkages to off-site clinics for repeat testing as well as active linkages to care and treatment, where appropriate

Phase II: Service Delivery—Step IV: Post-operative Counseling	
Objectives:	Ensure proper wound care and deliver risk reduction information
Primary Audience:	Male clients of VMMC
Key Messages:	▪ Keep your penis bandaged, dry, and pointing upward for 24 to 48 hours. ▪ Adhere to all post-operative care recommendations, including returning for follow-up visit two to seven days after surgery, as indicated by the clinical staff. ▪ Continue to keep the wound clean by using mild soap to clean the penis. ▪ Contact this number (_____) if you experience any of these warning signs... ▪ Follow the instructions on this appointment card, which indicates where and when your follow-up appointment(s) will occur. ▪ Abstinence from sexual intercourse/masturbation is necessary for six weeks. ▪ VMMC must be combined with other strategies to prevent HIV transmission.
Suggested IEC Tools:	▪ Brochure reiterating the above key messages ▪ Appointment card with emergency number and follow-up visit information
Phase II: Service Delivery—Step V: Routine Follow-up Counseling	
Objectives:	Ensure proper wound healing, and reinforce risk reduction messages
Primary Audience:	Male clients of VMMC
Key Messages:	▪ VMMC is only partially (approximately 60%) protective against HIV infection and condoms will need to be used consistently and correctly after your wound has healed. ▪ Abstinence from sexual intercourse and masturbation is necessary for six weeks. ▪ Please contact this number (_____) if you experience any problems or adverse events (AEs). ▪ Here are male/female condoms for use once you re-engage in sexual activity. ▪ Female partners deserve respect; intimate partner violence is unacceptable.
Suggested IEC Tools:	▪ Brochure reiterating the key messages outlined above ▪ Appointment card for follow-up visit
Phase III: Ongoing Risk Reduction Communication	
Objectives:	To ensure that circumcised men heal safely, champion VMMC, and increase the consistent practice of safer sexual behaviors following the procedure
Primary Audience:	Men who have been circumcised through VMMC
Key Messages:	▪ Abstain from sexual intercourse and masturbation for six weeks. ▪ Correct and consistent condom use is critical for preventing HIV—even after VMMC. ▪ Reduction of multiple and concurrent sexual partners will reduce risk of HIV infection. ▪ Use these active linkages for future HTC or HIV care and treatment (include a referral note[s], where needed).
Secondary Audience:	Female partners of VMMC clients
Key Messages:	▪ Use HIV prevention strategies regardless of partner's VMMC status.
Channels/Activities:	▪ Short message service (SMS) text messaging campaigns

APPENDIX 4: CHECKLIST ON VMMC COUNSELING

Pre-operative VMMC Counseling

☐ VMMC offers only 60% protection and must be combined with other strategies to prevent HIV transmission.

☐ VMMC is the surgical excision of the foreskin under local anesthesia.

☐ Circumcised men still need to practice risk reduction strategies after VMMC surgery.

☐ VMMC does not protect the client's partner(s) from HIV.

☐ Correct and consistent condom use is critical.

Demonstration of male and female condoms should be performed, unless the client is too young.

☐ HIV testing and STI screening are part of the VMMC evaluation.

☐ HIV test results are confidential.

☐ Post-operative care during the VMMC recovery period requires hygienic wound care and abstinence from all sexual intercourse and masturbation for six weeks after VMMC surgery.

☐ Risk reduction strategies (e.g., correct and consistent condom usage, reduction of multiple and concurrent partnerships) are important in order to stay HIV-negative.

☐ HIV testing of sexual partners is very important.

☐ Female partners deserve respect, and intimate partner violence is unacceptable.

☐ VMMC is different from traditional male circumcision.

Discussion of this topic will depend on the cultural context.

☐ Re-explore understanding of HIV and VMMC and correct any misconceptions.

☐ Provide psychological support to any clients in distress.

☐ Encourage and offer assistance with disclosure of HIV status to partner(s).

☐ Encourage partner/family testing.

☐ HIV-positive clients can be circumcised, but VMMC will not reduce the risk of transmitting HIV to partner(s). The healing process may be longer for HIV-positive clients; so, proper wound care is important.

Discussion of this topic will depend on the client's HIV status.

Immediate Post-operative VMMC Counseling (same day as VMMC surgery)

☐ Keep your penis bandaged, dry, and pointing upward for 24–48 hours.

☐ After 24–48 hours, you may see some blood through the dressing, but this is normal.

☐ If there is bleeding, hold your penis in your hand and apply a clean facecloth with mild pressure for 10–15 minutes.

☐ If bleeding continues/is severe, visit your local clinic as soon as possible.

☐ Follow the instructions on the appointment card indicating where and when your follow-up appointment(s) will occur.

☐ Adherence to post-operative recommendations, especially attending your follow-up appointment, is important.

☐ Once the bandage has been removed, clean your wound at least twice a day—immediately after showering or bathing—to prevent infection.

☐ Contact the emergency number and/or visit a local clinic if you experience complications.

☐ Abstinence from all sexual intercourse and masturbation is necessary for six weeks after VMMC surgery. Having sex prior to six weeks can damage the wound, result in an infection, and put you and your partner at high risk of getting HIV and/or STIs.

☐ VMMC offers only 60% protection and must be combined with other strategies to prevent HIV transmission.

Post-operative VMMC Counseling (on Day 2–7 after VMMC surgery)

☐ VMMC offers only 60% protection and must be combined with other strategies to prevent HIV transmission.

☐ Abstinence from all sexual intercourse and masturbation is necessary for six weeks.

☐ Risk reduction strategies (e.g., correct and consistent condom usage, reduction of multiple and concurrent partnerships) are important to prevent HIV transmission.

☐ Contact the emergency number and/or visit a local clinic if you experience complications.

☐ Here are male and female condoms for use once you re-engage in sexual activity six weeks after the date of your VMMC surgery.

APPENDIX 5: ADVERSE EVENT CLASSIFICATION AND GRADING

Adverse Event (AE) Type (abbreviation code noted below each type)	Timing of Initial Diagnosis (Check only one box.)	Severity of Initial Diagnosis Check as many boxes as applicable. Severity classification is determined by the highest column in which any box is checked. Not all boxes in column need to be checked to qualify.		
		Mild (1)	**Moderate (2)**	**Severe (3) *****
Excessive bleeding (BL)	Bleeding was diagnosed: ▪ Intra-operative or immediately post-operative (prior to discharge from clinic) = **Code A** ▪ After discharge from clinic and up to 30 days post-operative = **Code B** ▪ Greater than 30 days post-operative = **Code C**	▪ Bleeding that requires minimal intra-operative attention? ▪ Bleeding that requires less than 10 minutes of direct pressure to control?	▪ Bleeding that requires significant intra-operative effort to control? ▪ Bleeding that requires extra pressure dressing to control? ▪ Unscheduled return to the clinic for medical attention? (not just for reassurance)	▪ Surgical re-exploration for ligation or cauterization of bleeding vessels? ▪ Hospitalization? ▪ Transfer to another facility? ▪ Transfusion? ▪ Any hemodynamic instability?
Infection (IN)	Infection was diagnosed: ▪ Within the 30 days post-operative = **Code B** ▪ Greater than 30 days post-operative = **Code C**	▪ Mild erythema and minimal serous discharge from wound ▪ Only topical antibiotics used ▪ Infected area less than 1 cm in length	▪ Purulent discharge from wound ▪ Oral or IV antibiotics needed ▪ Infected area greater than 1 cm in length	▪ Abscess ▪ Severe cellulitis ▪ Wound necrosis ▪ Severe wound disruption ▪ Tissue loss
Pain (PA)	Pain was noted: ▪ Intra-operative or immediately post-operative (prior to discharge from clinic) = **Code A** ▪ After discharge from clinic and up to 30 days post-operative = **Code B** ▪ Greater than 30 days post-operative = **Code C**	▪ Mild discomfort	▪ Moderate discomfort ▪ Pain requiring interruption of operation for additional local anesthetic ▪ Pain resulting in inability to work or cancellation of normal activities lasting for four to seven days after surgery	▪ Pain resulting in early termination of VMMC or administration of general anesthesia ▪ Pain severe enough to result in inability to work or cancellation of normal activities lasting at least eight days after surgery
Swelling of penis/ scrotum, including hematoma (SH)	Swelling was noted: ▪ After discharge from clinic and up to 30 days post-operative = **Code B** ▪ Greater than 30 days post-operative = **Code C**	▪ Significant circumferential swelling along incision line (without bleeding) that resolves with time	▪ Localized swelling associated with some bleeding, resolves spontaneously (with or without pressure dressing)	▪ Surgical re-exploration for drainage of hematoma? ▪ Hospitalization? ▪ Transfer to another facility? ▪ Transfusion?

***Need to be urgently managed

Adverse Event (AE) Type (abbreviation code noted below each type)	Timing of Initial Diagnosis (Check only one box.)	Severity of Initial Diagnosis Check as many boxes as applicable. Severity classification is determined by the highest column in which any box is checked. Not all boxes in column need to be checked to qualify.		
		Mild (1)	Moderate (2)	Severe (3) ***
Anesthesia reaction or complication (AN)	Reaction was diagnosed: ▪ Intra-operative or immediately post-operative (prior to discharge from clinic) = **Code A**	▪ Palpitations, vasovagal reaction, or emesis managed with observation at VMMC clinic?	▪ Symptoms requiring medical intervention at clinic?	▪ Client transferred or referred to another facility for anaphylaxis or other anesthetic reaction? ▪ Client hospitalized for anaphylaxis or other anesthetic reaction?
Wound disruption/ dehiscence (WD)	Disruption was noted: ▪ After discharge from clinic and up to 30 days post-operative = **Code B** ▪ Greater than 30 days post-operative = **Code C**	▪ Disruption involving less than 1 cm	▪ Disruption involving up to 2 cm, but no surgical intervention	Wound disruption requiring additional surgery? ▪ Transfer to another facility? ▪ Hospitalization?
Damage to penis (DP)	Injury was noted: ▪ Intra-operative or immediately post-operative (prior to discharge from clinic) = **Code A** ▪ After discharge from clinic and up to 30 days post-operative = **Code B** ▪ Greater than 30 days post-operative = **Code C**	▪ Superficial burn or laceration	Significant laceration or burn requiring: ▪ Prolonged intra-operative attention to treat ▪ Extra pressure dressing ▪ Additional clinic follow-up care	Severe injury (amputation, laceration, urethral injury, significant tissue loss, or severe burn) requiring: ▪ Additional surgery? ▪ Transfer to another facility? ▪ Hospitalization? ▪ Transfusion?
Torsion of penis—new onset (TP)	Torsion was noted: ▪ After discharge from clinic and up to 30 days post-operative = **Code B** ▪ Greater than 30 days post-operative = **Code C**	▪ Torsion visible, but does not cause discomfort	▪ Torsion causes mild discomfort with erection, but no surgery needed	▪ Severe symptomatic torsion requiring re-operation

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Adverse Event (AE) Type (abbreviation code noted below each type)	Timing of Initial Diagnosis (Check only one box.)	Severity of Initial Diagnosis Check as many boxes as applicable. Severity classification is determined by the highest column in which any box is checked. Not all boxes in column need to be checked to qualify.		
		Mild (1)	**Moderate (2)**	**Severe (3) *****

Excessive skin removed (ES)	Excessive skin removal noted:
	▪ Intra-operative or immediately post-operative (prior to discharge from clinic) = **Code A**
	▪ After discharge from clinic and up to 30 days post-operative = **Code B**
	▪ Greater than 30 days post-operative = **Code C**
		▪ Intra-operative recognition of excess removal noted, but not enough to warrant additional surgical steps
		▪ Post-operatively, client complains of tightening, but physical exam is normal
			▪ Intra-operative recognition of excess removal noted, requiring either:
			  ▪ Mobilization of skin near wound margin
			  ▪ Placement of extra sutures for reinforcement
			▪ Post-operatively, tightening of the skin is discernible, but re-operation not required
				▪ Additional surgery required?
				▪ Transfer to another facility?
				▪ Hospitalization?

Insufficient skin removed (IS)	▪ Intra-operative or immediately post-operative (prior to discharge from clinic) = **Code A** ▪ After discharge from clinic and up to 30 days post-operative = **Code B** ▪ Greater than 30 days post-operative = **Code C**	▪ Prepuce (foreskin) extends over the coronal margin, but less than one-third of the glans is covered at rest in flaccid state	▪ Between one- and two-thirds of glans is covered by residual prepuce at rest in flaccid state	▪ Greater than two-thirds of glans is covered by residual prepuce at rest in flaccid state
Voiding problems (difficulty urinating) (VO)	Voiding problems noted: ▪ After discharge from clinic and up to 30 days post-operative = **Code B** ▪ Greater than 30 days post-operative = **Code C**	▪ Resolves spontaneously or with loosening of dressing	▪ Requires treatment in clinic—such as transient catheterization	▪ Requires surgical re-exploration for urethral injury or blockage ▪ Requires placement of suprapubic tube
Device application difficulty (DA)	▪ Intra-operative or immediately post-operative (prior to discharge from clinic) = **Code A**	▪ Could not apply device, changed to surgical method of VMMC	▪ Device caused mild bleeding or other mild AE, requiring change to surgical method of VMMC	▪ Device caused significant bleeding or other significant AE, requiring change to surgical method of VMMC
Device displacement or spontaneous detachment (DD)	▪ After discharge from clinic and up to 30 days post-operative = **Code B**	▪ Post-operative device displacement and bleeding, three or fewer sutures required	▪ Displacement or detachment and bleeding, more than three sutures required	▪ Device displacement or detachment, penile damage present

***Need to be urgently managed

Adverse Event (AE) Type (abbreviation code noted below each type)	Timing of Initial Diagnosis (Check only one box.)	Severity of Initial Diagnosis Check as many boxes as applicable. Severity classification is determined by the highest column in which any box is checked. Not all boxes in column need to be checked to qualify.		
		Mild (1)	Moderate (2)	Severe (3) ***
Occupational exposure of health care provider (OT)	▪ Intra-operative or immediately post-operative (prior to discharge from clinic) = **Code A** ▪ After discharge from clinic and up to 30 days post-operative = **Code B** ▪ Greater than 30 days post-operative = **Code C**	▪ Blood splashes on intact skin	▪ Needle stick ▪ Blood splatters in eye ▪ No illness as a result	▪ Any seroconversion or illness attributed to exposure
Other AE (describe) (OA) _____ _____	▪ Intra-operative or immediately post-operative (prior to discharge from clinic) = **Code A** ▪ After discharge from clinic and up to 30 days post-operative **= Code B** ▪ Greater than 30 days post-operative = **Code C**		▪ AE resulting in inability to work or cancellation of normal activities lasting for four to seven days after surgery	▪ AE severe enough to result in inability to work or cancellation of normal activities lasting for at least eight days after surgery ▪ Transfer to another facility? ▪ Hospitalization?

***Need to be urgently managed

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ADDITIONAL RESOURCES

Hankins C, Forsythe S, and Njeuhmeli E. 2011. Voluntary medical male circumcision: An introduction to the cost, impact, and challenges of accelerated scaling up. *PLoS Med* 8(11): e1001127. doi:10.1371/journal.pmed.1001127.

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