



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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MESSAGE FROM THE US GLOBAL AIDS COORDINATOR

Between 2009 and 2016, PEPFAR supported a cumulative total of 11.7 million voluntary medical male circumcisions (VMMC) for HIV prevention in the 14 priority countries in East and Southern Africa. This was approximately 56 percent of the 20.9 million circumcisions required to reach 80 percent coverage, as estimated in the Joint Strategic Action Framework 2012–2016. Reaching this goal will avert more than 240,000 HIV infections and will save USD\$4,400.00 in HIV treatment costs per HIV infection averted between 2015 and 2025.

The Impact Action Agenda of the U.S. President’s Emergency Plan for AIDS Relief (*PEPFAR 3.0—Controlling the Epidemic: Delivering on the Promise of an AIDS-free Generation*) highlights VMMC as one of the core biomedical prevention interventions, along with condom use, antiretroviral therapy and related diagnostics, and prevention of mother-to-child transmission. PEPFAR 3.0 embodies the push to control the HIV epidemic and realize the goal of an AIDS-free generation; and VMMC is an essential part of that initiative.

The second edition of the *PEPFAR Best Practices for VMMC Site Operations* updates guidance presented in the 2013 edition. Whereas the first edition focused on *setting up* VMMC sites, the second edition focuses on *establishing and supporting quality VMMC services for HIV prevention at the VMMC site level*, reflecting the maturity of the VMMC program and the number of sites already established. This entails solidifying the functionality and efficiency of existing VMMC sites. The document guides PEPFAR implementing partners with proven approaches for providing high-quality VMMC services specifically at the facility or VMMC site level and ensuring successful VMMC scale-up from the site level to the global level. It emphasizes strengthening or enhancing essential linkages among other men’s health services; increasing community-level support and participation; and using data to develop the most cost-effective use of available resources.

Achieving an AIDS-free generation will not be possible without including men in HIV prevention, care, and treatment. Men in sub-Saharan Africa face numerous health risks that have yet to be effectively addressed. HIV risks for men, especially young men, include unprotected sex and alcohol abuse, which are closely tied to cultural concepts that define masculinity, promote risk-taking, and underplay the value of health-seeking behavior. Men’s risks, in turn, affect girls and women, and increase their vulnerability to sexually transmitted infections, including HIV. Addressing men’s HIV risks while bringing them into the wider health care arena could have significant impacts on families, communities, and societies, including indirect benefits to the health of women and girls.

The guidance presented in this manual supports VMMC 2021, as articulated in the policy brief, *A Framework for Voluntary Medical Male Circumcision: Effective HIV Prevention and Gateway to Improved Adolescent Boys’ & Men’s Health in Eastern and Southern Africa by 2021*. This framework, developed by the World Health Organization and the Joint United Nations Programme on HIV/AIDS, includes VMMC as part of a package of essential interventions to decrease annual new HIV infections to 500,000 by 2021—a 75 percent reduction relative to 2010. These new strategic directions are a follow-on to the *Joint Strategic Action Framework 2012–2016*.

Specifically, VMMC 2021 seeks to target 27 million men for VMMC as part of *integrated sexual and reproductive health services for men*—a gateway service to prevent HIV while also welcoming men into the health care arena.



Reaching VMMC 2021 goals will entail not only accelerating the scale-up of VMMC, but also developing new VMMC-based platforms for meeting the sexual and reproductive health needs of men and boys. The expectation is that bringing men the health care they will improve their wellbeing while indirectly benefiting women and girls, thus contributing to the goal of an AIDS-free generation. The DREAMS (Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe) Initiative, which targets partners of adolescent girls and young women, is designed to meet this goal. VMMC thus offers an excellent opportunity to bring men into health care, link HIV-positive men to treatment, and expand their access to the full range of clinical services.

The updated manual also reflects PEPFAR's Phase 3 (PEPFAR 3.0) goals of achieving sustainable control of the HIV epidemic and reaching the globally accepted 90-90-90 goals by 2020. PEPFAR endorses a data-driven, strategic approach that maximizes the effectiveness of investments in HIV interventions; accelerates the scale-up of HIV prevention; and engages all social resources (government, communities, and the private sector) in partnerships to address HIV and improve social wellbeing.

The revision of this manual has been a community enterprise, with input from many experts in the field of VMMC for HIV prevention. PEPFAR particularly acknowledges the contributions and leadership of the VMMC Technical Working Group at the Office of the Global AIDS Coordinator; the unwavering support of the Strengthening High Impact Interventions for an AIDS-free Generation Project; the careful reviews received from PEPFAR and other U.S. Government field offices; and the country-specific case studies contributed by field experts.

PEPFAR implementing partners have a tremendous challenge ahead of them to reach the goal of circumcising 27 million men by 2021. The rewards will be enormous, with millions more lives saved and a tidal shift in HIV incidence and prevalence. PEPFAR encourages implementers at the site service level to use this guidance, which highlights successful approaches and describes key steps in successful implementation of high-quality VMMC services. Our hope is that the manual will serve as a resource for PEPFAR partners as they build on current success in VMMC; support men's inclusion in health care and health decisions; and contribute to global goals in HIV prevention, treatment, and containment.

Ambassador Deborah L. Birx, MD

U.S. Global AIDS Coordinator



CHAPTER I.

Introduction & Background to Edition 2

This document provides implementing partners supported by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) with a collection of the best resources available for sites providing voluntary medical male circumcision (VMMC) for HIV prevention. This version is Edition 2; Edition 1, released in 2013, focused on assisting implementing partners and site staff with opening new VMMC service locations. The first version covered all aspects of the planning, launch, and oversight of daily operations at the site level. Given the maturation of VMMC programs since 2012, Edition 2 focuses on optimizing management of existing service locations, though chapters still remain for those establishing new sites. The primary intended audience for Edition 2 remains site-level staff, with different chapters most relevant to different staff positions.

Optimized management includes renewed attention to safety and quality of the services provided; technological innovation and efficiencies in service delivery techniques; and strategies for the age pivot (to males aged 15 to 29 years) and the geographical pivot (to DREAMS districts and non-DREAMS scale-up districts with high HIV burden and low male circumcision prevalence) to contribute to epidemic control, to name a few. [See [PEPFAR DREAMS](#)].

DREAMS was launched on World AIDS Day in December 2014 and is an ambitious \$385 million public-private partnership to reduce HIV infections among adolescent girls and young women in 10 sub-Saharan African countries. The goal of DREAMS is to help girls develop into **D**etermined, **R**esilient, **E**mpowered, **A**IDS-free, **M**entored, and **S**afe women. Girls and young women account for 71 percent of new HIV infections among adolescents in sub-Saharan Africa. The 10 DREAMS countries (Kenya, Lesotho, Malawi, Mozambique, South Africa, Swaziland, Tanzania, Uganda, Zambia, and Zimbabwe) account for nearly half of all the new HIV infections that occurred among adolescent girls and young women globally in 2014.

Since 2013 standards of care have changed, and new PEPFAR policies have been introduced covering issues like tetanus risk mitigation, age requirements for certain surgical techniques, and enhanced adverse event (AE) reporting requirements. Two medical devices, PrePex and ShangRing, have also been prequalified by the World Health Organization (WHO) for use by VMMC programs since the release of Edition 1. These updated/new topics are covered in this revised version. In addition to an update of the technical content, this document gives attention to increasing utilization by enabling web-based and mobile access. While the print version appears much the same, the e-platforms have been designed for “point-and-click” functionality, so that resources are more readily available to the broadest possible audience of VMMC sites and staff.

As in the first edition, the second edition has included new best practices of VMMC service provision from across the 14 priority countries. These have been summarized and placed in the respective chapters.

In addition, each chapter is designed as a stand-alone resource covering all aspects of the respective topic, including:

- **Chapter Goals:** States the objectives of the chapter.
- **What Users Need to Know:** Summarizes the most important information and referenced documents with links (online version) or directions (printed version) to the tools/instruments/resources.
- **Frequently Referenced Information:** Additional relevant content embedded into the body of the text.
- **For Additional Information:** Provides additional details on the topic for those who want more.
- **Tools, Instruments and Guidance Documents:** Lists all the resources referenced in the chapter.
- **Case Studies:** Provides program examples where applicable.
- **References:** Lists the manuscripts cited in the chapter.

The printed version of this guide will be made available on the AIDSFree website. The tools, instruments, and guidance documents referenced throughout are available on the web through links that take you directly to the information of interest.

The array of materials referenced in this collection have been sourced from Joint United Nations Programme on HIV/AIDS (UNAIDS) and WHO guidance, the PEPFAR Voluntary Medical Male Circumcision Technical Working Group (VMMC TWG), and 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 scaling up VMMC services at the above site (national VMMC program), see [WHO Operational Guidance for Scaling Up Male Circumcision Services for HIV Prevention](#).

BACKGROUND

VMMC reduces men's risk of acquiring HIV through heterosexual intercourse by approximately 60 percent.¹ As more men get 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. The indirect protection for women is substantial; modeling at levels of 80 percent circumcision coverage shows an approximately equal number of HIV infections will be averted in women as in men after 15 years (Njeuhmeli, Forsythe, Reed, et al. 2011). 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.

WHO and UNAIDS determined 14 VMMC priority countries which all have high HIV burden and low male circumcision prevalence (WHO and UNAIDS 2007). These countries are all in Eastern and Southern Africa (Botswana, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Namibia, Rwanda, South Africa, Swaziland, Tanzania,

¹ Auvert, Taljaard, Lagarde, et al. 2005; Bailey, Moses, Parker, et al. 2007; Gray, Kigozi, Serwadda, et al. 2007; Mehta, Li, Moses, et al. 2012; Kong, Kigozi, Ssempija, et al. 2011; Gray, Kigozi, Kong, et al. 2012; Mehta, Moses, Agot, et al. 2013.



Uganda, Zambia, and Zimbabwe) and are scaling up VMMC, with 11.7 million men and boys circumcised by the end of 2015. According to VMMC modeling presented at the 2016 International AIDS Conference in Durban, South Africa (Njeuhmeli 2016), these VMMCs are projected to avert a total of 450,000 infections by the end of 2030, even assuming that countries achieve UNAIDS 90-90-90 targets for scaling up ART. And if the 14 priority countries continue to scale up VMMC to reach 80 percent coverage by 2020 and maintain coverage at this level thereafter, these VMMCs will avert an additional 470,000 HIV infections by 2030, bringing the total HIV infections averted up to 922,000 (Ibid.).

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.² One of the primary benefits of VMMC for female partners is its association with a reduction in penile human papillomavirus (HPV), which is associated with cervical cancer in female partners (Castellsagué, Bosch, Muñoz, et al. 2002; Wawer, Tobian, Kigozi, et al. 2011).

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.³ Because VMMC provides only partial protection from acquiring HIV, it is necessary for circumcised males to minimize any potential increased risky sexual behaviors following VMMC provision (known as risk compensation). Risk compensation, however, has not been shown to increase following circumcision.⁴

In order to ensure that VMMC is provided as part of a comprehensive HIV prevention package, WHO recommends that all VMMC clients receive the minimum package of services [See [WHO Manual for Male Circumcision Under Local Anaesthesia, 1st edition](#)], including:

- Offering of HIV testing services (HTS)
- 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 or device removal of the foreskin).

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

- Identifying and implementing active referral and linkages of HIV-positive men to HIV care and treatment and STI services
- Assuring voluntarism and informed consent.

²Weiss, Thomas, Munabi, et al. 2006; Tobian, Serwadda, Quinn, et al. 2009; Auvert, Blake, Maseko, et al. 2012; Nasio, Nagelkerke, Mwatha, et al. 1996; Johnson, Sherman, Ssempiija, et al. 2009; Gray, Serwadda, Tobian, et al. 2009; Pintye, Baeten, Manhart, et al. 2014; Mahiane, Legeai, Taljaard et al. 2009; Hernandez, Wilkens, Zhu, et al. 2008; Castellsagué, Bosch, Muñoz, et al. 2002; Auvert, Sobngwi-Tambekou, Cutler, et al. 2009; Gray, Serwadda, Kong, et al. 2010; Wiswell and Hachey 1993.

³Auvert, Taljaard, Lagarde, et al. 2005; Bailey, Moses, Parker, et al. 2007; Gray, Kigozi, Serwadda, et al. 2007.

⁴Westercamp, Agot, Jaoko, et al. 2014; Mattson, Campbell, Bailey, et al. 2008; Gray, Kigozi, Kong, et al. 2012; Harper 2016; Maughan-Brown and Venkataramani 2012; Riess, Achieng, Otieno, et al. 2010; Abbott, Haberland, Mulenga, and Hewett 2013.

As VMMC programs continue to mature, some aspects of VMMC are taking on new importance: for example, demand creation to balance supply and demand, continuous quality improvement to ensure high quality and safety of VMMC services, and follow-up and tracking/monitoring of adverse events. The majority of men seeking VMMC are uninfected with HIV. It will be important to tailor messages to help HIV-negative men remain uninfected while HIV-positive men identified at VMMC sites are appropriately referred and linked to HIV care and treatment and STI services.

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ABBREVIATIONS

AE	adverse event
HIV	human immunodeficiency virus
HPV	human papillomavirus
HTC	HIV testing and counseling
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
STI	sexually transmitted infection
UNAIDS	Joint United Nations Programme on HIV/AIDS
VMMC	voluntary medical male circumcision
VMMC TWG	PEPFAR Voluntary Medical Male Circumcision Technical Working Group
WHO	World Health Organization



CHAPTER 2.

Service Site Selection, Planning, Preparation, and Launch

CHAPTER GOALS

To ensure staff are able to:

- Select appropriate locations/facilities to serve as VMMC service delivery sites.
- Develop shared understanding, ownership, and support among the facility management, administration, VMMC program staff, and the community.
- Prepare the site for launch of VMMC services that meet the minimum WHO/UNAIDS, PEPFAR, and national standards.
- Ensure a smooth start-up of new VMMC services.
- Reinforce the knowledge, attitudes, and skills of new VMMC teams, and ensure that they have the necessary confidence, skills, and systems to provide quality services.

WHAT USERS NEED TO KNOW

Before starting VMMC implementation, it is critical to ensure that appropriate facilities/locations are selected to serve as VMMC service delivery sites. Selected sites must be able to provide all components of the VMMC minimum package of services [[WHO Manual for Male Circumcision Under Local Anaesthesia, 1st edition](#)] and meet other criteria set and agreed upon by stakeholders in the country [See [Site Selection Criteria Tool](#)]. Site selection is followed by a careful assessment of the site's ability to perform the full VMMC minimum package of services [See [Site Readiness and Preparation Tool](#)]. Site staff are responsible for ensuring availability of all resources, including the definition of roles and responsibilities for all staff [See [Site Action Plan Tool](#)]. Once VMMC services begin, assessments of quality through external quality assessment (EQA) and continuous quality improvement (CQI) [See [EQA Instruments and CQI Self Assessment Tool](#)], should commence immediately and occur on a regular schedule for as long as clients are receiving VMMC services at the site. [Table 2.1](#) depicts the sequence of steps leading to the first day of service delivery, and [Table 2.2](#) shows the relative timing of these early activities in the overall scheme of site operations.

FREQUENTLY REFERENCED INFORMATION

Table 2.1. Phases in Site Selection, Planning, and Preparation

Table for Tracking Key Activities for Opening a New VMMC Service Delivery Location

SITE SETUP ACTIVITIES	WHEN (START DATE MINIMUM)	NEEDS	RESPONSIBLE STAFF	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 start date	Site map		
Supplies to new site	7 working days before start date	Supply checklist Receiving form		
Site setup—setting up rooms, tents, etc.	5 working days before start date	Site setup guide, including tent or marquee setup		
Site readiness assessment	3 days before start date	Site readiness tool		
Site orientation	First day of service	Orientation package, objectives		

Table 2.2. Site Action Planning Template/Tool: Timing of Overall Site Operations, including Early Activities Leading to Service Start

ACTION ITEM	PROJECTED PERIOD OF IMPLEMENTATION (MONTHS)												TOOLS
	1 ST	2 ND	3 RD	4 TH	5 TH	6 TH	7 TH	8 TH	9 TH	10 TH	11 TH	12 TH	
Service site selection													
Site assessment													Site assessment tool
Site-specific feedback													Optional site report
Service site preparation													
Adequate space: rooms, lighting, client flow													Site action plan template/tool
Site set-up/reorganization plan, orientation (site action planning)													Site action plan template/tool
Staffing													
Numbers adequate (doctors, nurses, counselors, etc.)													Site action plan template/tool
Training completed													
Mentoring, use of tools, SOPs, guidelines, etc.													Site action plan template/tool
Procurement of commodities													
List of commodities													Tools from supply chain/logistics team
Procurement of commodities													
Emergency kit													
VMNC skills training													
Clinical skills training													WHO Manual for Male Circumcision under Local Anaesthesia, 1st edition

ACTION ITEM	PROJECTED PERIOD OF IMPLEMENTATION (MONTHS)												TOOLS
	1 ST	2 ND	3 RD	4 TH	5 TH	6 TH	7 TH	8 TH	9 TH	10 TH	11 TH	12 TH	
TIME IN MONTHS													
Counseling and communication skills training													Counseling Guide
Creating demand													
Creating demand-training													
Creating demand—IEC (information, education, and communication) materials													
Creating demand—for VMMC services													
Implementation of WHO VMMC minimum package													WHO Manual for Male Circumcision under Local Anaesthesia, 1st edition
Support launch of VMMC services													
Routine monitoring, reporting and evaluation													
Data collection													
Reporting													
Continuous quality improvement (CQI)													WHO Quality Toolkit
External quality assessment (EQA)													EQA Tools
Adverse event management, monitoring, and reporting													PEPFAR Reporting Protocol for Notifiable Adverse Event
Health care waste management													

Download an [Excel version of the Site Action Planning Template](#) on AIDSFree's website.



FOR ADDITIONAL INFORMATION

SERVICE SITE SELECTION

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 or burden of HIV and male circumcision coverage in the catchment area; in general, areas with higher male HIV prevalence and lower male circumcision coverage are preferable, as the impact of scaling up VMMC is greater. An area with lower ART coverage might also be preferred over a similar one with higher coverage, because transmission of HIV will be more intense in such an area.
- The size and density of the catchment population; initially, men in dense population areas may be easier to attract to VMMC services.
- Sub-district, district, provincial, and national support for selected site or area (for fixed or mobile services).
- An estimate of unmet need for VMMC (based on estimated male population, male circumcision prevalence, HIV prevalence).
- Expected demand for VMMC services [See [Chapter 4](#)].
- Potential physical space that can be dedicated (temporarily or permanently) to VMMC services, including school classrooms, churches, government buildings, or space for a tent or extension of an existing building.
- 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 and availability of skilled human resources.
- Accessibility of sites/facilities by the target population.
- The types 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:
 - » Sexually transmitted infection clinics
 - » Emergency services

- » Employer or worksite occupational health centers
- » voluntary counseling and testing (VCT) centers
- » Primary health care clinics, including antenatal care clinics where men may accompany their partners
- » 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 may include:
 - » HIV care and treatment sites for those who test HIV-positive
 - » Clinics able to perform post-operative care
 - » Regional tertiary hospitals for management of adverse events that exceed the capabilities of the VMMC site.
- 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, the site location, 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 staff positions based upon 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:

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 or outreach services. 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 they cannot dedicate existing space. In these instances, additional space needs to be created by using semipermanent structures or tents.
- b. **Mobile sites** are sites where the commodities and staff are moved from one site to another (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 combined with outreach services. 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 only at certain times of the year (seasonal demand), or as additional sites in an area with other existing site types when a VMMC campaign temporarily increases demand. Mobile sites are usually temporary structures, often tents and prefabricated structures or trucks ([Figure 2.2](#)).
- i. **Basic tents** are easy to install and are movable, though they may have poor air circulation and are generally not durable. These tents are most often used for HIV testing services (HTS) at the VMMC site. Although tents can provide very flexible space for service provision when they are present, procuring tents can pose a significant delay to programs if adequate lead time is not planned.

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 HTS or FU services, set up adjacent to the fixed site, can provide space where clients can be tested or reviewed for follow-up visits without crowding the fixed site.
 - Creating extra space dedicated solely to VMMC surgery at a fixed health care site.
- ii. **Mobile trucks/vans** are used to provide VMMC services on board; also known as “clinics on wheels” ([Figure 2.1](#)). Mobile trucks are built with fully equipped VMMC clinics that are partitioned to include necessary room for screening, counseling, operating, and recovery rooms. The truck is chauffeured to a specific area and parked, and services commence on board. Some services such as registration and health education may be conducted outside the truck, in a tent, under a shade, or in an existing structure. The duration of stay is determined by demand and how the team has planned. It may be parked for one day, one week, or other time period. It may also come in every day.

- iii. **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, semipermanent 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.
- c. **Outreach sites** may be used during periods 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, such as in areas with limited infrastructure and in “hard-to-reach” areas. They are different from mobile sites in that they can be permanent structures (e.g., primary clinic, school, or community center), modified for VMMC purposes. In sites that may be rural and far from a fixed site, tents or prefabricated structures may be used to increase available space and allow more clients to receive VMMC services. A “hub and spoke” approach can be used for 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 than fixed sites alone, as services can be offered in an area according to demand or 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 at selected site** ensures the availability of VMMC services at existing (fixed) 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 consistent levels throughout the year.
- b. **Campaign service delivery at selected sites** provides VMMC services in high-volume places 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 or seasons). 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. It should be noted that any type of service delivery, routine or campaign, may be conducted at any of the three types of sites, either at fixed, mobile, or routine.

For more information on effective campaigns and their impact on provision of services, see the articles, “Voluntary Medical Male Circumcision: Translating Research into the Rapid Expansion of Services in Kenya, 2008–2011,” [Mwandi 2011] and “Voluntary Medical Male Circumcision: Matching Demand and Supply with Quality and Efficiency in a High-Volume Campaign in Iringa Region, Tanzania” [Mahler 2011]. For efficiency in campaign planning, there is a need to preplan all the sites beforehand so that no time is wasted in selecting sites again once the campaign is under way. In some programs,

all sites are preselected before the campaign, including sites where services will move in case demand runs low in the main sites. Thus there are “satellite” sites for each “mother” site and all needs for the additional sites are projected beforehand. This “hub-and-spoke” model saves the time the team would spend to find additional sites once the campaign is underway.

Note: The service delivery focus may change depending on the maturity of the program. For example, at the beginning of the program, when there is much demand for VMMC services, campaigns are the best approach since they may reach a large number of males in a relatively short period of time. As the program matures and demand for VMMC services decreases, conducting campaign-based services may not be the most efficient use of resources. Instead, mobile and outreach services may be the best approach to reach men in their communities. Static sites may always be needed since that is where most providers are based and they need to continue circumcising even in small volumes to ensure that they don't lose their skills.

3. Determine the Staffing Options

- a. **The HR staffing lists** that follow ([Table 2.3](#)) 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 through the public sector via task shifting, and volunteer medical staff from other countries (Curran 2011).

Figure 2.1. Using Mobile Trucks/Vans for VMMC Service Provision



Figure 2.2. Examples of a Medical Examination Room and Tents



Table 2.3. Human Resource Staffing Options for High-, Middle-, and Low-Volume Surgical Sites

ITEMS	HIGH-VOLUME SITES	MIDDLE-VOLUME SITES	LOW-VOLUME SITES
Beds	8+	4–7	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 Provider ¹	2	1	1
Nurse 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
Counselor—can overlap with trained nurses for efficiency	3 (minimum)	2 (minimum)	Shared role
Expert Client	2	1	N/A
Community Health Worker	8–10	5–8	1–4

ITEMS	HIGH-VOLUME SITES	MIDDLE-VOLUME SITES	LOW-VOLUME SITES
Runner	1	1	Shared role
Data Clerk	1	1	Shared role
Receptionist	1	1	Shared role
Driver (for mobile sites)	1	1	N/A

Notes:

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 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.

SERVICE SITE PLANNING

Once a site has been selected, a thorough approach to site preparation can greatly affect a VMMC program's success. Conducting a thorough site readiness assessment, will guide what is needed to get the site “operational” [See [Site Readiness and Preparation Tool](#) and [Site Action Plan Tool](#)]. 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 uses 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 used community health workers as mobilizers for demand creation and client follow-up visits.

The site readiness 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 Readiness and Preparation Tool](#) should be used to evaluate:

- The current state of basic services (e.g., infection prevention, waste disposal, and monitoring and evaluation) [See [Male Circumcision Waste Management Plan](#)]
- The space identified for VMMC services and the map of client flow ([Figure 2.3](#)) [See [Site Readiness and Preparation Tool](#)]
- The catchment area and to 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 postoperative care to manage adverse events (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 [SCMS E-catalog](#)].

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 HIV testing center (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; preprocedure clinical screening; VMMC procedure; post-operative care and counseling; reviews and follow-up services; data management; waste management, [Male Circumcision Waste Management Plan](#); and infection prevention.
- 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 for temporary space if needed.

Based on the findings of this assessment, the team should work together to develop a detailed VMMC Site Action Plan [See [VMMC Site Action Plan Tool](#)] to get the site ready to provide safe VMMC services. The site action plan provides a clear outline of what must be completed (by whom and when) 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 to be responsible for ensuring that each task is complete. The site action plan should be based on a clear understanding of how the services will be provided, and it should link community demand creation [See [Chapter 4](#)] with clinical service provision [See [Chapter 6](#)]. This [VMMC 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. Site orientation is used to sensitize all staff to VMMC for HIV prevention services; it 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. The orientation may 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.

SERVICE SITE PREPARATIONS

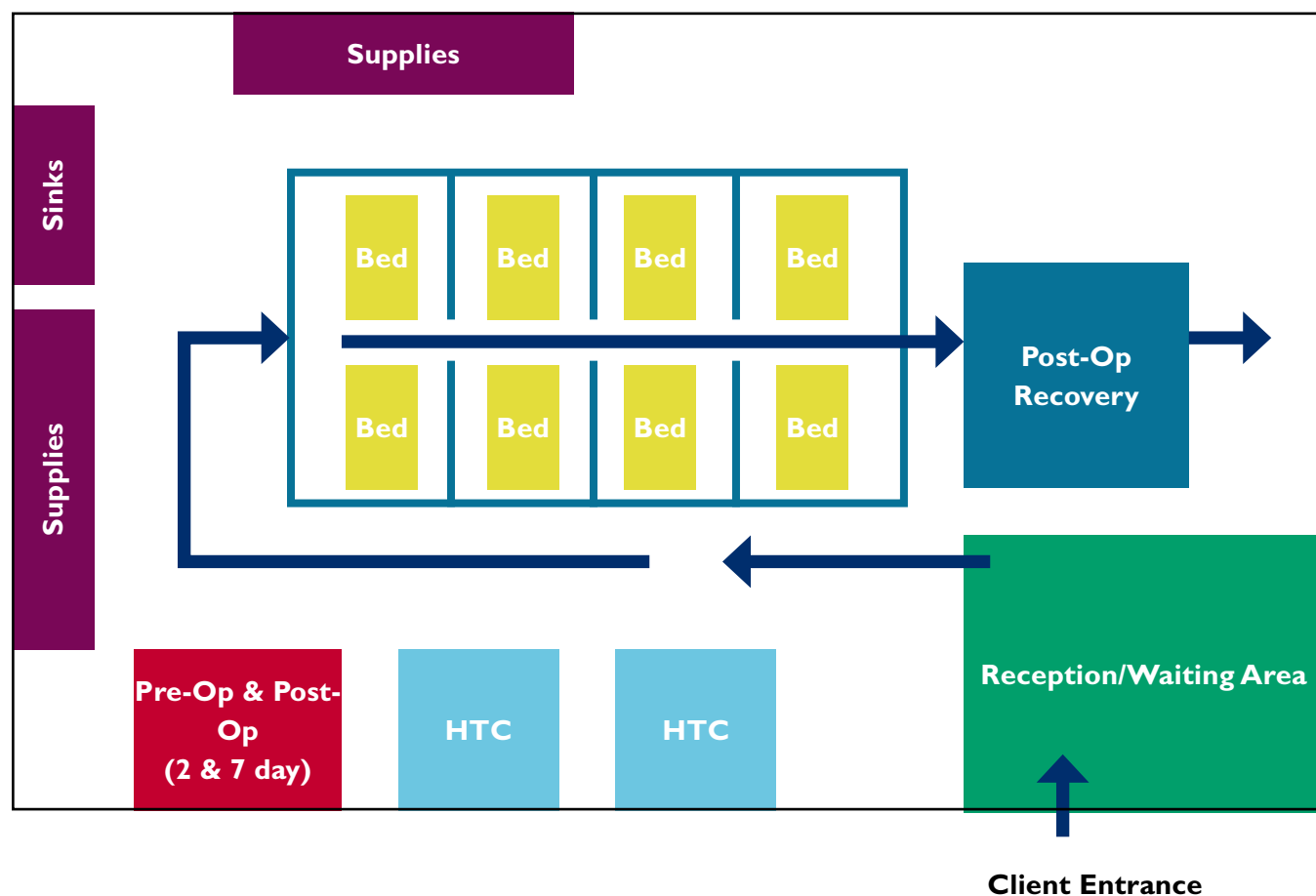
It is essential that the site's facilities, equipment, and commodities are ready to provide VMMC services **before** staff are trained to provide VMMC services [See [SCMS E-catalog](#)]. Training is most effective when the learned skills are put to use immediately after training. Staff should complete 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, 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 remodeling, procurement of equipment and supplies, reshuffling of staff, or hiring additional staff. Specific training may also be conducted, such as training in infection prevention and control. All the parties involved should report on their responsibilities; 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 [VMMC Service Site Preparation Planning Template](#)].

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 ([Table 2.3](#)). With good planning, existing space can often be improved—with little infrastructural modification—to maximize utilization of space and improve client flow.

Figure 2.3.VMMC Client Flow Diagram

Large static 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.

SERVICE SITE LAUNCH

VMMC staff should begin providing VMMC services as soon as possible after training has been completed and providers pass competency assessments. By this point in the timeline, the VMMC site will have been prepared and demand generation activities will have begun [See [Chapter 4](#)]. 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 (e.g., counseling, clinical, etc.), if they are not already experienced in providing VMMC services, it is important to provide them with immediate on-site support and mentoring by a proficient VMMC provider, ideally by one of their trainers [See [Chapter 5](#)]. 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 help orient the team to the standards for quality service provision [See [CQI Self Assessment Tool](#) and [EQA Instruments](#)], and help ensure early and ongoing incorporation of efficiency models such as those proposed by WHO [See [Considerations for Implementing Models for Optimizing the Volume and Efficiency of Male Circumcision Services \(MOVE\)](#)].

CASE STUDIES

[Case Study 2.1. Setting Up Private VMMC Clinics in Namibia](#)

[Case Study 2.2. Opening and Coordinating New VMMC Sites in Hard-to-Reach Areas in Tanzania](#)

TOOLS, INSTRUMENTS & GUIDANCE DOCUMENTS

1. [WHO Manual for Male Circumcision Under Local Anaesthesia, 1st edition](#)
2. [Site Selection Criteria Tool](#)
3. [Site Action Plan Tool](#)
4. [Site Readiness and Preparation Tool](#)
5. [EQA Instruments](#)
6. [CQI Self-Assessment Tool](#)
7. [Male Circumcision Waste Management Plan](#)
8. [Site Assessment Tool](#)

9. [USAID Global Health Supply Chain Program-Procurement and Supply Management \(GHSC-PSM\) project's online e-Catalog](#)
10. [VMMC Service Site Preparation Planning Template](#)
11. [Considerations for Implementing Models for Optimizing the Volume and Efficiency of Male Circumcision Services \(MOVE\)](#)

REFERENCES

- Curran, K, et al. 2011. "Voluntary Medical Male Circumcision: Strategies for Meeting the Human Resource Needs of Scale-Up in Southern and Eastern Africa." *PLOS Medicine* 8(11): e1001129. doi: 10.1371/journal.pmed.1001129.
- Mahler, HR, et al. 2011. "Voluntary Medical Male Circumcision: Matching Demand and Supply with Quality and Efficiency in a High-Volume Campaign in Iringa Region, Tanzania." *PLOS Medicine* 8(11): e1001131. doi: 10.1371/journal.pmed.1001131.
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ABBREVIATIONS

AE	adverse event
CQI	continuous quality improvement
EQA	external quality assessment
HR	human resources
HTC	HIV testing center
HTS	HIV testing services
IEC	information, education, and communication
MOVE	models for optimizing volume and efficiency
SCMS	Supply Chain Management System
SD	start date
VCT	voluntary counseling and testing

CASE STUDY 2.1.

Setting Up Private VMMC Clinics in Namibia

The majority of medical doctors in Namibia are practicing in the private sector. Namibia's private medical sector is robust, with well-established facilities that include outpatient consulting rooms.

Figure 2.1.1. Establishing new VMMC sites



In October 2014, through funding from PEPFAR and the USAID SHOPS Project (Strengthening Health Outcomes through the Private Sector), SHOPS/Namibia embarked on a program to engage private medical providers to contribute to the national VMMC scale-up strategic plan. They conducted meetings and information sessions town by town and after 10 months, 45 providers had expressed interest in joining the network of providers.

To understand provider competencies and areas of improvement, initial site assessments were conducted that consisted of an assessment of the entire facility's resources, management structure, provision of the minimum package of VMMC services, quality improvement systems, emergency supplies and level of emergency preparedness, waste management protocol, and infection prevention and control practices. Whereas private facilities were of a very high standards ([Figures 2.1.1.](#) and [2.1.2.](#)), they were not optimally using their resources, including space, staff, and supplies.

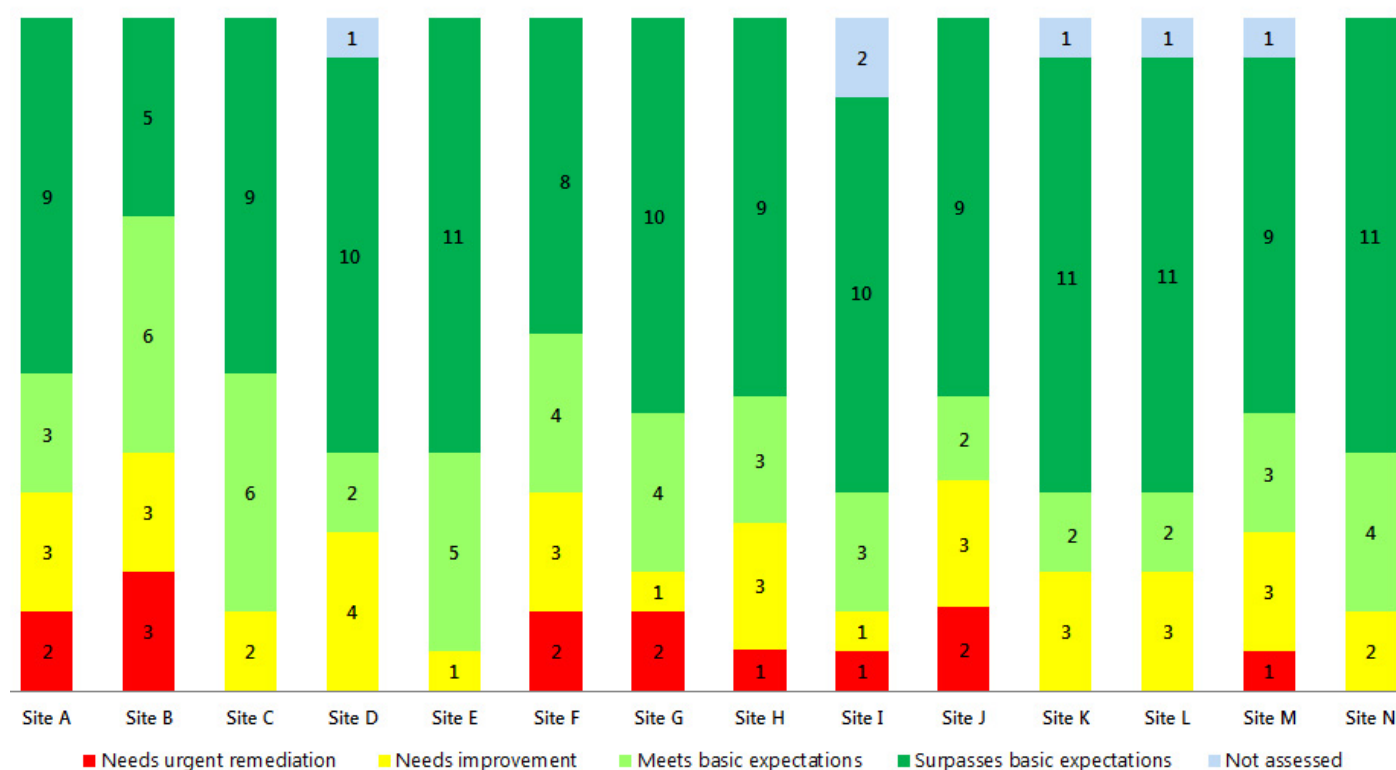
Following this assessment, the sites received onsite coaching to scale up VMMC services by an experienced VMMC private provider and a demand creation expert. Every new entry into the network received orientation on inventory management of VMMC commodities, emergency preparedness, and the WHO VMMC minimum package of services. SHOPS/Namibia mobilized insurance companies to agree on a standard VMMC tariff that would cover the VMMC WHO minimum package of services, allowing all the insured clients to be covered for VMMC.

There was a clear growth in VMMC numbers in these sites, with some sites reporting monthly VMMC numbers as high as the cumulative total for the previous calendar year. The network of private providers has also continued to grow, with more medical doctors throughout the country expressing their interest to be enrolled.

The main lessons learned through working with private providers were:

1. Private providers (SHOPS) contribute to a pool of providers that are scarce in Namibia, where VMMC must be conducted by medical doctors only.
2. SHOPS had sufficient resources to conduct VMMCs immediately and, although they were all low volume sites, the network combined greatly contributed to the total national coverage.
3. SHOPS providers are able to reach clients who are usually older and working and who may not otherwise seek services from public facilities.
4. SHOPS sites are open longer hours and weekends, hence allowing clients to receive services any time at their convenience.

Figure 2.1.2. Site Readiness Assessment of Private Health Facilities for VMMC Services in Namibia



CASE STUDY 2.2.

Opening and Coordinating New VMMC Sites in Hard-to-Reach Areas in Tanzania

In Tanzania, the AIDSFree Project with funding from PEPFAR under USAID, supports the Ministry of Health, Community Development, Gender, Elderly and Children (MHCDGEC) to provide VMMC services in three regions, Iringa, Njombe, and Tabora. The program is well established and has conducted almost 500,000 VMMCs. In 2014–15, the program provided VMMC services in 488 sites (hospitals, health centers, and dispensaries). Many sites were used, as VMMC services were needed in hard-to-reach areas, because the more accessible areas had reached or surpassed VMMC saturation. The program employed three primary modalities of VMMC services: static sites, outreach (mobile), and campaigns.

With a large number of sites used in a year, the team has streamlined opening new sites to ensure high quality and efficient service delivery. The team employed modified approaches depending on the type of site being opened. The approaches are as follows.

To open new static sites: The team reviewed key data such as population (residents) of the catchment area (number of wards, villages) and also reviewed potential demand for a site. Often the data are pulled from the GIS system that was developed for the program. A short list of potential sites was then identified. The team—comprising technical and demand creation personnel, a data manager, District Medical Officers, District AIDS Control Coordinators, a District Health Management Information System focal person, and the government regional VMMC focal person—conducted an assessment of the proposed site. This tool addressed power availability, infection prevention and control practices, human resources, community leadership, security, integrated services, existing programs, and linkage to care. Shortly after the assessment, the team discussed and selected qualified sites. A needs assessment list was developed, an MOU was drafted, and the team prepared for site opening.

To open new outreach or campaign sites: AIDSFree used a hub and spoke model for campaigns using a “mother” hub site with spinoff spokes known as “baby” sites. The mother sites stayed open throughout the campaign and housed providers and supplies, while new baby sites were opened and closed as demand fluctuated throughout the campaign. New sites were selected by the demand creation team in the weeks before the campaign. The VMMC team then started the services while observing recommended standards. Once demand in a baby site began to decline, the next site that was already identified opened the next day. Key to this approach was having an adequate number of VMMC providers at the mother site to support the baby sites and having enough equipment at the mother site (including emergency kits) to support two to three baby sites.

CHAPTER 3.

Commodities, Procurement & Supply Chain Considerations

CHAPTER GOALS

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

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

WHAT USERS NEED TO KNOW

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

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

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

10 STEPS IN THE PROCUREMENT PROCESS:

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

FREQUENTLY REFERENCED INFORMATION

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

<https://www.ghsupplychain.org/for-suppliers/products>

A section of the webpage is included as a worksheet on [page 38](#) to show readers the information provided on the website.

FOR ADDITIONAL INFORMATION

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

PROCUREMENT

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

STEPS OF THE PROCUREMENT PROCESS

Site Level

- **Definition of Specifications:** Project managers and site managers must be knowledgeable about the appropriate items needed for their program and must be able to procure the correct commodities. The PEPFAR VMMC TWG has developed the specifications of commodities to be used in PEPFAR-funded VMMC programs. PEPFAR partners should procure commodities in line with those specifications. The specifications can be found in the SCMS E-catalog. [See [USAID Global Health Supply Chain Program-Procurement and Supply Management \(GHSC-PSM\) project's online e-Catalog](#)]. Updated references will be provided should new procurement agencies determine that alterations in commodities and supply chain processes are necessary.

Above Site Level

- **Creation of price request and price quotation:** This item refers to steps that are needed to identify the products and quantities requested, as well as the terms of sale and the type and location for the transfer of goods. [See [PFSCM Client Toolkit](#) and [GHSC-PSM Client Intro Letter](#)]. 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 addition to accurate information, clear specifications of the product required (with product codes), quantities needed, and requested time of delivery should be provided.

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- **Approval of price quote:** The acceptance of the price quote requires the signature of a designated U.S. Government representative and is normally resolved quickly. Several steps can be taken to ensure the timely approval of a price quote: clearly defining the specifications, determining correct initial assessments of program commodity needs and expected client demand, and assuring the complete understanding of the VMMC program implementation plan and its needs for commodities. Communicating all the site's needs up front will prevent having to repeat the steps above, thus reducing or preventing delays.
- **Purchase order/sales order creation:** After the approval of the quote, the site manager or procurement officer can work with the project manager to develop a purchase order. This process should take anywhere from a few days to a few weeks, though delays can occur due to product unavailability.
- **Vendor lead time (manufacturing time):** This item, which specifies the time needed by the vendor to secure the commodity requested, varies among product lines. Vendor lead time is minimal when products are in stock, or it can take several months if a product must be custom designed or manufactured to order. When developing the purchase order/sales order, it is important to confirm that the items are in stock so that time lag in delivery can be kept to a minimum.
- **Shipping documents creation:** This process creates the shipping and importation documents that are needed to move the cargo to its destination. The provision of accurate partner and destination information is critical in this step. This procedure can be problematic for newly launched VMMC programs that need to order a product before a supply chain and logistics plan has been developed. However, shipments that move forward without accurate information can be delayed in the customs process for months.
- **Customs preclearance procedures:** This item refers to the steps necessary to secure permits or waivers for importing health-related commodities. These procedures change by country, and lead times range from very quick to extremely lengthy. Country regulations should be verified before placing orders to prevent delays and also to minimize the approval procedure.
- **Delivery to port of entry:** Time required to complete this process can vary depending on the mode of transportation selected, the distance between supplier and client, and the availability of services in the countries where the producer and the receiver are located. For certain items and situations (large, bulky, items with a long shelf life, such as VMMC kits with a 24–30 month shelf life), a slower method of transportation will be selected (e.g., ocean, truck), and for others a faster alternative should be used (e.g., air).
- **Customs clearance:** The time required to complete this procedure, which takes place at the port of entry, should be short if all preclearance requirements have been fulfilled. In cases where shipping occurs before verification of regulations, this procedure can take a very long time—or could even lead to merchandise detention. In most African countries, customs clearance will take a couple of days, but this can vary from country to country.
- **Local delivery to warehouse:** Once the cargo has been cleared through customs, it will be transported to the storage warehouse. The time required to complete this step can depend on distance, mode of transportation, and destination country, among other factors. In addition, the need to distribute stock to multiple warehouses in one country can further delay this process.

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

LOGISTICS

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

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

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

VMMC KITS

Key to commodity procurement are decisions about whether to use a single, completely disposable kit that includes all the surgical instruments and consumables required to perform one VMMC procedure or to use a combination kit that comprises a pack of single-use supplies (gauze, needles, scalpel blade, gloves, etc.) and a set of reusable surgical instruments that can be sterilized and reused [See [USAID Global Health Supply Chain Program-Procurement and Supply Management \(GHSC-PSM\) project's online e-Catalog](#)]. It is important to note that the PEPFAR VMMC TWG has developed standards for seven VMMC kits. These kits have been standardized to allow economies of scale, accepted quality standards, and the possibility of stocking kits in regional distribution centers to reduce lead time. The seven kits are:

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

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

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

VMMC KITS WITH SINGLE-USE INSTRUMENTS	VMMC KITS WITH REUSABLE INSTRUMENTS
ADVANTAGES	
<ul style="list-style-type: none"> – Ensure high-quality, sterile content in both nonhospital and hospital settings – Logistically and operationally easier, especially in mobile outreach services – Reduce initial startup program costs – Eliminate autoclave maintenance, personnel, training, and other costs – Consumables and single-use instruments can be combined into one kit – Can be bundled to ease ordering and managing of supplies – Increase service delivery efficiency. 	<ul style="list-style-type: none"> – Ensure high-quality, sterile content in both nonhospital and hospital settings – Well-maintained reusable instruments may be easier to use than single-use stainless steel instruments – Build health system capacity and infrastructure – Employ local personnel – Create less waste and thus less need for waste management procedures – Require fewer long-term resources to procure additional instruments.
DISADVANTAGES	
<ul style="list-style-type: none"> – Create substantial amounts of waste, including stainless steel instruments that require smelting or burying, thus raising environmental concerns – Limit the flexibility of clinicians to use their preferred equipment and surgical method – Are prone to losing some contents to theft, which could compromise the sterility of the remaining contents. 	<ul style="list-style-type: none"> – Require additional staff time for cleaning, sterilizing, and packaging instruments and for monitoring procedures – Require autoclave availability and regular maintenance for sterilization – Require water and power supply at site of autoclaving – May require additional time for procurement because kits are secured from multiple sources – Initial cost may be high.

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

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

TOOLS, INSTRUMENTS, & GUIDANCE DOCUMENTS (9)

- 1. [PEPFAR Male Circumcision Partners’ Meeting: Commodities and Improved Coordination of Male Circumcision for HIV Prevention](#)
- 2. [USAID Global Health Supply Chain Program-Procurement and Supply Management \(GHSC-PSM\) project’s online e-Catalog](#)
- 3. [Quantification, Forecasting, and Monitoring Basic Tool for VMMC](#)
- 4. [Costing Tool for Public Hospitals—Male Circumcision Model](#)
- 5. [GHSC-PSM Client Intro Letter](#)
- 6. [PFSCM Client Toolkit](#)
- 7. [Automated Directives System \(ADS\) 312 USAID Pharmaceutical Approval Process](#)
- 8. [GHSC-PSM VMMC Order Sheet](#)

REFERENCE

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

ABBREVIATIONS

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

EXCERPT FROM SCMS/PEPFAR E-CATALOG

VOLUNTARY MEDICAL MALE CIRCUMCISION

Ordering VMMC products from SCMS:

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

The PEPFAR VMMC TWG recommends the following [VMMC kits and device](#):

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

Additional Products for VMMC Programs

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

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

Order Lead Time for Kits

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

Voluntary Medical Male Circumcision Health Care Waste Management Toolkit

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

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

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

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



CHAPTER 4.

VMMC Communication at the Site Level and Demand Creation

CHAPTER GOALS

To ensure that site-level staff are able to:

- Provide key audiences in the community with accurate and complete information about VMMC to build demand and enable eligible men to make an informed choice.
- Communicate essential information on voluntary medical male circumcision (VMMC) and HIV prevention clearly and comprehensively at appropriate stages of the client's visit.
- Identify and correct any myths and misconceptions about VMMC, and address any fears/concerns about the procedure.
- Instruct the client on and ensure comprehension of postoperative measures to ensure safety and proper healing.
- Provide communication and counseling tailored to the client (based on his age, life phase, and other needs).
- Provide each client with high-quality services that result in customer satisfaction and peer referrals.
- Provide general information on successful demand creation strategies and considerations.

WHAT USERS NEED TO KNOW

COMMUNICATION AT SITE LEVEL

VMMC services offer a unique opportunity to engage adolescent and adult males in high-quality HIV prevention communication and services; and to share key messages with males who otherwise might not interact with the health system. Consistent communication and counseling throughout these VMMC services is critical for capitalizing on this opportunity. This reference guide helps to ensure that in-service communication and counseling content is comprehensive and standardized across PEPFAR's (U.S. President's Emergency Plan for AIDS Relief) VMMC country programs [See [Best Practices Guide: VMMC In-Service Communication](#)].

Given the large number of topics that need to be covered at each phase of the VMMC service (group education preoperative, individual counseling, immediate postoperative, follow-up visit), checklists are available as a tool for ensuring consistency and accuracy of communication and services [See [Checklist on VMMC Counseling](#)]. For those VMMC sites where a device is offered as a circumcision method, device-based VMMC warrants tailored

in-service communication to ensure that clients are aware of the unique attributes of the device-based procedure—device placement, wearing of the device, device removal, and recovering from device-based circumcision and wound healing by secondary intention. A device-specific counseling checklist is also available [See [Checklist on Counseling for VMMC with Device](#)]. Circumcision with a device method where the foreskin is left in situ and removed several days after application (elastic collar clamp) should be undertaken only if the client is adequately protected against tetanus by immunization with tetanus-toxoid-containing vaccine (TTCV) [See [Tetanus and Voluntary Medical Male Circumcision: Risk According to Circumcision Method and Risk Mitigation, Report of the WHO Technical Advisory Group, 12 August 2016](#).] Finally, counselors should be aware of myths about VMMC and be ready to address them. A list of frequently asked questions is also available [See [VMMC Frequently Asked Questions \(FAQs\)](#)].

DEMAND CREATION

Demand creation can be defined as strategic interventions that reinforce motivating factors and help the target audiences overcome key barriers, with the aim of increasing service uptake. Community engagement, mass media, and advocacy are critical components of VMMC demand creation; they require close coordination with services.

Demand creation is part of a broader package of communication interventions. It's important to ensure consistency of information disseminated across the VMMC continuum [See [Phases and Steps for VMMC Demand Creation](#)].

Successful demand creation follows communication best practices and includes the following elements:

- A clearly defined communication and demand creation strategy, informed by research, that outlines key barriers and motivators, primary and secondary audiences, channels, and key messages. In most countries, the communication plan will include a strategic mix of channels and approaches, such as community engagement, mass media, infection prevention and control materials, and advocacy with leadership and influential agents, among other approaches. [See [Communication Strategy for Voluntary Medical Male Circumcision in Kenya](#); [Communication Materials Adaptation Guide](#); [A Guide to Working with the Media to Promote VMMC in Kenya](#); [VMMC Video Discussion Guide](#); and [VMMC Demand Creation Toolkit](#).]
- Outreach scaled to align with the availability of services.
- Communication through multiple channels that engages the target population and key influential people, including partners, parents or guardians, employers, and other individuals and groups that can influence the VMMC decision. Such channels include community radio, social media, interpersonal peer communication, and TV shows with a panel of VMMC experts.
- Tailored messages and communication channels that resonate with younger and older men, both in and outside of relationships (segmenting audience and influencers for more effective demand creation).
- Engagement of women by providing tailored information about VMMC's benefits for women and their key role as mothers and partners.
- Clearly written, attractive brochures and leaflets printed in the local language, targeted to specific audiences, such as parents and partners.

- 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). Male friends and peers can be strong advocates.
- Monitoring community mobilization to ensure the quality and consistency of messages, and to follow up with potential clients who do not present for services.
- Communication campaigns that can be adjusted, as needed, to match the volume of services that can be provided; similarly, services that can be scaled up to keep pace with the demand created by advocacy, sensitization, and mobilization.
- Consistent reporting, collection, and analysis of data to inform demand creation.

The following activities can be used to monitor communication:

- Track the communication activities to assess how well plans are being implemented. This may include materials produced and disseminated, media intensity index, and reporting of community mobilizer action plans, among others. This information can be triangulated with service uptake to see where demand creation activities are on target or need modification.
- Use referral slips to further strengthen monitoring of demand creation efforts and closer linkages to specific activities [See [Sample VMMC Referral and Follow-Up Card](#)].
- At the site level, collect data at client intake to determine where the client heard about VMMC and what motivated him to come for services. Analyze these data on a regular basis to inform demand creation activities and resource allocation [See [Sample VMMC Client Intake Registration Form](#)].

FREQUENTLY REFERENCED INFORMATION

Figure 4.1. Checklist on VMMC Counseling For Surgical Clients

Adapted from: Annex 4: Checklist on VMMC Counseling in [PEPFAR's Best Practices for Voluntary Medical Male Circumcision Site Operations: A Service Guide for Site Operations, First Edition, 2013](#).

This is an illustrative checklist. Note that redundancy of some items in different sections of the counseling is intentional, as repeating the same information at different points helps clients to internalize messages.

Preoperative VMMC Counseling

- ☐ VMMC is different from traditional male circumcision. VMMC is the removal of the foreskin, performed by surgery or by device, depending which services are available and on client eligibility.
- ☐ VMMC offers only partial protection from HIV acquisition (60%).
- ☐ Circumcised men still need to practice risk reduction strategies after VMMC surgery.
- ☐ Risk reduction strategies for staying HIV-negative include correct and consistent condom use, reduction of multiple and concurrent partnerships, and not using alcohol before sex.

Condoms demonstrations should be performed for sexually active and age-appropriate clients seeking VMMC, and should align with local policies.

- ☐ HIV-positive men can be circumcised, but VMMC will not reduce the risk of transmitting HIV to their partners.
- ☐ Confidential HIV testing and sexually transmitted infection (STI) screening are part of the VMMC evaluation. HIV testing, while recommended, is optional. Clients may still be circumcised regardless of their HIV test result, if they are deemed healthy enough for surgery.
- ☐ HIV testing of sexual partners is also very important.
- ☐ If a patient has symptoms of an STI, he will receive treatment and be asked to come back another day for the surgery.
- ☐ Postoperative care during the VMMC recovery period requires hygienic wound care to prevent infections.
- ☐ Healing takes up to six weeks. There is an increased risk of STI/HIV transmission, and of damaging the wound, if men have sex during healing.
- ☐ We recommend against masturbating or having sex at all during the healing period. Unprotected sex during that time is especially risky.
- ☐ Patients should discuss VMMC's benefits with their partners, and the importance of the postoperative abstinence period.
- ☐ Re-explore understanding of HIV and VMMC and correct any misconceptions.

Discussion of this topic will depend on the cultural context. For clients who test HIV-positive:

- ☐ Provide psychological support to any clients in distress; and provide active referral to care and treatment services.
- ☐ Encourage and offer assistance with disclosure of HIV status to partners.
- ☐ Encourage partner/family testing.
- ☐ HIV-positive clients can be circumcised, but VMMC will not reduce the risk of transmitting HIV to partners. The healing process may be longer for HIV-positive clients, so proper wound care is important.

Immediate Postoperative 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.
- ☐ Do not apply any home remedies to the wound, such as animal dung or ash, or any substance that is not prescribed by the health care provider. Home remedies will increase the risk of infection, including tetanus infection, which can be deadly.
- ☐ Do not pull on or scratch the wound while it is healing.
- ☐ Avoid strenuous physical work for the first five days after surgery.
- ☐ Follow the instructions on the appointment card indicating where and when your follow-up appointment(s) will occur.
- ☐ Attend follow-up appointments, as instructed by the VMMC clinicians.
- ☐ 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.
- ☐ Return to the clinic immediately if you have any of the following symptoms: continued bleeding that does not stop or gets worse; swelling of the penis and/or testes; increased pain, fever, tenderness in the groin; pus from the wound; difficulty passing urine; hardness/stiffness of the lower abdomen; stiffness of the jaw.
- ☐ The safest approach for protecting your own health and the health of others is to completely abstain

- ☐ from sexual activity for six weeks after VMMC surgery. If you are absolutely unable to abstain, masturbation poses less risk than sexual intercourse, though it may increase the time it takes for the wound to heal. If for any reason you have sex in the next six weeks—which is strongly discouraged for you and your partner, for safety reasons—you must use a condom.
- ☐ If you believe healing is complete before the six-week healing period is over, then return to your provider to be assessed for healing status and possible return to sexual activity.
- ☐ VMMC offers only 60 percent protection and must be combined with other strategies to prevent HIV transmission.

Postoperative VMMC Counseling (on Day 2–7 after VMMC Surgery)

- ☐ VMMC offers only partial protection (60%) and must be combined with other strategies to prevent HIV transmission.
- ☐ Risk reduction strategies for staying HIV-negative include correct and consistent condom use, reduction of multiple and concurrent partnerships, and not using alcohol before sex.
- ☐ Abstinence from all sexual intercourse and masturbation is highly recommended for six weeks.
Note: Identify whether the client has had any difficulties adhering to the prescribed six-week abstinence period, and work with him on plans to address these difficulties.
- ☐ Do not apply any home remedies to the wound, such as animal dung or ash. This will increase risk of infection, including tetanus.
- ☐ Contact the emergency number and/or visit a local clinic if you experience complications.
- ☐ There are male and female condoms for use once you reengage in sexual activity six weeks after the date of your VMMC surgery.

Source: Annex 4: Checklist on VMMC Counseling in *PEPFAR's Best Practices for Voluntary Medical Male Circumcision Site Operations: A Service Guide for Site Operations, First Edition, 2013*.

CASE STUDIES

[Case Study 4.1. Overcoming Seasonality in Scaling Up VMMC in Iringa, Tanzania](#)

[Case Study 4.2. Call Center Optimizes Uptake of Clinical Services in South Africa](#)

[Case Study 4.3. Integrating VMMC into Local Community Structures, Breaking Cultural Barriers in Malawi](#)

[Case Study 4.4. Partnering with Private Employers on Provision of VMMC Services in Tanzania](#)

[Case Study 4.5. Mwami Mulembe \(Stylish Man\) Campaign in Uganda](#)

TOOLS, INSTRUMENTS & GUIDANCE DOCUMENTS

1. [Best Practices Guide: VMMC In-Service Communication](#)
2. [Checklist on VMMC Counseling](#)
3. [Checklist on Counseling for VMMC with Device](#)
4. [VMMC Frequently Asked Questions \(FAQs\)](#)
5. [Communication Strategy for Voluntary Medical Male Circumcision in Kenya](#)
6. [Communication Materials Adaptation Guide](#)
7. [A Guide to Working with the Media to Promote VMMC in Kenya](#)
8. [VMMC Video Discussion Guide](#)
9. [VMMC Demand Creation Toolkit](#)
10. [Sample VMMC Client Intake Registration Form](#)
11. [Sample VMMC Referral and Follow Up Card](#)
12. [Phases and Steps for VMMC Demand Creation](#)

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ABBREVIATIONS

ART	antiretroviral therapy
GIS	geographic information systems
HIV	human immunodeficiency virus
HTC	HIV testing and counseling
MCHIP	Maternal and Child Health Integrated Program
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
RHSP	Rakai Health Sciences Program
STI	sexually transmitted infection
VMMC	voluntary medical male circumcision

CASE STUDY 4.1.

Overcoming Seasonality in Scaling Up VMMC in Iringa, Tanzania

PROBLEM

A qualitative study in Tanzania's Iringa region conducted in 2011 by the Maternal and Child Health Integrated Program (MCHIP) found that seasonal considerations were of major importance to a client's decision about voluntary medical male circumcision (VMMC) (Plotkin et al. 2011). Most clients had a strong preference for circumcision in the colder months of June, July, and August. The main reason cited for this preference was the belief that cooler weather promotes wound healing. To meet targets and use resources most efficiently, it became critical to overcome the seasonality barrier and make sites productive year-round.

IMPROVEMENT APPROACH

MCHIP and the Ministry of Health and Social Welfare developed a new strategy to increase service uptake in the “off season” (i.e., warmer months) through five key components:

1. Focus on taking services to more remote rural sites.
2. Use GIS (geographic information systems) mapping to identify the best sites for outreach campaigns.
3. Collaborate with local school officials in these areas to release students during service delivery periods.
4. Use men circumcised during the “off season” as peer promoters, who share their experiences with uncircumcised peers and testify to their healing process through interpersonal communication and testimonials on local radio.
5. Conduct VMMC outreach campaigns year-round, rather than just during the high season as before.

RESULTS

In 2010, 88 percent of VMMCs were performed in the three winter months. By 2014, that proportion had spread across other months, and was down to 28 percent during winter months. The data demonstrating a major shift in seasonality are supported by observations of health providers, who noted changes in attitude toward seasonality and circumcision among both clients and providers. Recent qualitative research, conducted in the Njombe and Tabora Regions with males and female partners/mothers, also points to a decrease in seasonality as a salient issue.



CASE STUDY 4.2.

Call Center Optimizes Uptake of Clinical Services in South Africa

CareWorks (a social purpose enterprise that provides HIV treatment and workplace programs in South Africa) established an outbound call center that provides telephone support to optimize uptake of clinical services in South Africa. Proactively contacting men who show an interest in VMMC, and assisting them with booking and follow-up support, ensures an enhanced user experience, resulting in increased uptake and the likelihood that the male client will promote services to his peers.

Because the call center is database-driven and performance is managed by proprietary data systems, CareWorks is able to use the systems and staff to process, track, and monitor campaigns to increase demand for VMMC. Unique “please call me” numbers are assigned to campaigns, allowing monitoring of outcomes.

One recent campaign strengthened by the call center was the peer-to-peer campaign in which recently circumcised men were encouraged to mobilize their peers for VMMC. Messages were sent to males aged 15–49, encouraging them to refer three friends/family members for VMMC to earn 30 rand worth of cellphone airtime. Call center agents contacted respondents to get details on referrals. Airtime was paid for three viable leads (interested males, aged 15–49 and uncircumcised), regardless of whether they became circumcised or not. The call center supported the referred men through the booking process. Using sampled groups within the database, the call center sent messages to 600 circumcised men, of whom 11 percent responded to the message. One hundred seventy-seven referrals were made, resulting in 30 circumcisions (17 percent completion). A further 48 males were booked or ready to book for VMMC, and were supported by the call center through the booking process.

A second campaign used community media to promote VMMC services. A press release promoting VMMC was picked up by local community media houses. The campaign incurred minimal costs to release the story, and received a relatively good response rate. Allocating a unique number on the release meant that the 120 responses could be tracked, attributing 30 circumcisions to the campaign.



CASE STUDY 4.3.

Integrating VMMC into Local Community Structures, Breaking Cultural Barriers in Malawi

PROBLEM

Under its mandate to provide VMMC services in three PEPFAR-supported districts in Malawi, PSI/Malawi faced many cultural barriers, centered on the fact that targeted communities were already traditionally circumcising.

IMPROVEMENT APPROACH

To overcome the cultural barriers, PSI/Malawi (Population Services International, a global health services organization) integrated community structures into demand creation activities. At the district level, PSI held entry meetings with district executive committees. At the community level, meetings were conducted with traditional leaders, traditional circumcisers (*Angaliba*), health surveillance assistants, and other stakeholders (e.g., community-based organizations). These people and structures were very important in influencing decisions in the communities. The aim of these meetings was to ensure that districts and communities were well prepared, and that critical community buy-in was in place before service delivery began.

A key approach of PSI/Malawi was to recruit community mobilizers who were local to the target community. People were comfortable directing questions about VMMC to their fellow community members, as was evident in discussions and interpersonal communication activities that generated much interest and many questions. The use of satisfied VMMC clients, who were considered role models for potential clients, also emerged as a best practice. Local mobilizers were a great help in debunking myths about VMMC (e.g., VMMC leads to sterility in men).

RESULTS

Using this strategy of integrating community structures, PSI/Malawi demonstrated good results. For example, Blantyre District implemented the strategy in January 2015 and subsequently noted that the weekly average number of circumcisions for May–June 2015 (167) was significantly higher than for the same time period in 2014 (112). In Chiradzulu and Mangochi Districts, some traditional circumcisers voluntarily brought clients to VMMC clinics. Most of the clients were those who intended to undergo traditional circumcision.



CASE STUDY 4.4.

Partnering with Private Employers on Provision of VMMC Services in Tanzania

In rural Tanzanian villages where people depend on agriculture for their livelihoods, the cotton ginnery is a respected and rare employment opportunity. IntraHealth International liaised and teamed up with the Alliance Cotton Ginnery in Kasoli village to provide VMMC services among the employees and men in the surrounding community. In collaboration with the District Health Management Team and the ward and village/hamlet leaders, the VMMC team worked closely with the ginnery management and employees to plan for service delivery and resource sharing.

Ginnery authorities took a lead in mobilizing their employees and other locals in the surrounding communities to access VMMC services. The ginnery provided space for setting up and delivering VMMC services within their complex. Employees who received circumcision services were granted 14 days of leave to recover without docking their pay. Of the 1,926 men circumcised and tested for HIV, 30 (about 2%) were adult male ginnery staff, representing nearly 80 percent of the factory's employees.

Through this partnership, the cotton ginnery strengthened its relationship with the surrounding communities and gained goodwill among its employees, and further enhanced its good reputation in the community. The employees benefited from this collaboration by getting free VMMC services while still receiving their daily wages. The implementing partner shared costs for service provision and logistical arrangements for setting up VMMC space and other community mobilization activities.

Keys to successful partnership with the cotton ginnery were carefully identifying opportunities where everyone involved would benefit; carefully planning services; sharing and planning for resource contribution; and involving district and community leaders in the initiative.



CASE STUDY 4.5.

Mwami Mulembe (Stylish Man) Campaign in Uganda

Mwami Mulembe (Stylish Man) was a coordinated social and behavior change communication campaign that used a combination of mass media and interpersonal communication to increase demand for VMMC services and condom use among men of all ages in Rakai district, Uganda. Clients included high-risk groups such as fishermen and mobile transport workers. The pilot campaign, launched in early 2014, reconceptualized the ideal Ugandan man as a “stylish man”—one who cares about pleasing his partner while simultaneously taking care of his health and personal hygiene.

This one-year pilot campaign used a combination of approaches, including a popular radio program for men broadcast live from a “man van” that toured the 54 communities where the Rakai Health Sciences Program (RHSP) conducts its surveys. In each community Stylish Man committees organized local competitions during which men were referred for HIV testing services, VMMC, and antiretroviral therapy services offered through local health facilities and mobile clinics organized by RHSP. Men who used services received vouchers allowing them to enter the Stylish Man contest that took place live during the man van visits. The man van program included music, games, and stories from “stylish men” and their partners/wives; and encouraged men to use mobile services provided free of charge at the man van site. The grand finale of each man van visit was the Stylish Man contest, during which four or five men who had received vouchers for using Stylish Man services were invited to take part in a quiz on stage. The winner in each community was crowned “Stylish Man.” This portion of the program was recorded and broadcast during each Stylish Man weekly radio program. Stylish Man winners were interviewed, often together with their wives/partners, and featured during radio spots and videos played during future Stylish Man shows, on radio, and in video clubs in Rakai.

The campaign ran from June 2013 until February 2014. According to annual results of the Rakai Community Cohort Study from 2005 through 2014, VMMC uptake increased by 12 percent between 2013 and 2014—three times the average annual increase (4% per year) over the previous seven years (Gray et al. 2007).



CHAPTER 5.

VMMC Skills Training & Training of Supervisors

CHAPTER GOALS

To give voluntary medical male circumcision (VMMC) service providers the required competencies to provide a full package of VMMC services, according to national, World Health Organization/Joint United Nations Programme on HIV/AIDS (WHO/UNAIDS) and U.S. President's Emergency Plan for AIDS Relief (PEPFAR) standards. These competencies include the following:

- Group education and individual counseling on VMMC and human immunodeficiency virus (HIV) risk reduction
- Pre-procedure clinical eligibility screening.
- Pain control using appropriate weight-based dosing of local anesthetic agents
- Povidone iodine skin preparation with two-minute drying time before circumcision
- Immediate post-procedure clinical monitoring
- Clinical follow-up including diagnosis, management and referral of adverse events
- Training and use of emergency commodities to handle any potentially severe/life threatening adverse events, and/or having developed in advance and able to utilize a rapid referral plan for more advanced levels of medical care, as needed
- Referral and active linkage of VMMC clients identified as HIV-positive at VMMC sites to HIV care and treatment services as well as other services, such as STI treatment
- Use of safe injection techniques
- (For supervisors) Provide supportive supervision for other service providers.

WHAT USERS NEED TO KNOW

To maintain the highest level of quality and safety required of an elective surgical/clinical program, all those providing services at the site must have completed and been deemed competent by a recognized in-service training program in providing the full minimum package of VMMC services, including clinical circumcision services, as well as HIV testing, risks/benefits of circumcision, risks of complications, post-procedure hygiene, wound care, and

abstinence counseling. [See [Chapter 6—Providing the VMMC Minimum Package of Services \(Tables 6.1 and 6.2\)](#)].

Providers should be specifically trained in eligibility screening, including medical history, physical examination, screening for sexually transmitted infections (STIs), tetanus vaccination history, and tetanus risk. The actual circumcision procedure must be by a WHO-recognized method, including forceps-guided (for males older than 14 years), dorsal slit, sleeve resection, or a WHO-prequalified medical device for adolescent or adult VMMC. Programs using electrocautery for hemostasis must provide adequate training in both electrocautery and placement of ligating sutures ([Table 5.1](#)). Special attention during training is given to weight-based dosing of local anesthetic for pain control, with particular emphasis on the correct technique for injection of local anesthetic (aspiration before EVERY injection of anesthetic agent to ensure the needle is not in a blood vessel or the corpus cavernosum). Safe injection training also addresses the problem of “double-dipping” and reuse of anesthetic vials, needles, or syringes between patients [See [Chapter 9](#)].

Providers are trained on clinical follow-up, including screening, documentation, diagnosis, management, and reporting of adverse events. While numerous VMMC for HIV prevention curricula exist throughout the sub-Saharan region, all must be based on core knowledge and skills outlined by WHO [See [WHO Manual for Male Circumcision Under Local Anaesthesia, 1st edition](#)]. Supplemental training information has also been developed that sites should use to ensure providers are up to date on the current standard of practice, such as identification and management of adverse events [See [COSECSA/PSI VMMC AE Action Guide](#)] and correct use of electrocautery [See [Manual for Use of Electrocautery in VMMC](#)]. Training material specific to VMMC counseling should also be used [See [VMMC Counseling Training Package](#)].

Site-level refresher training in best practices [See [VMMC Video: Implementing Best Practices](#)] and basic VMMC science [See [Global Health e-Learning Course—Male Circumcision: Policy and Programming](#)] may be useful for identifying opportunities for innovation and ensuring retention of basic knowledge. For sustainability of the program, existing supervision systems should also be strengthened; those responsible for supervising VMMC service providers may benefit from supportive supervision training [See [Supervising Healthcare Services: Improving the Performance of People](#)] and tools for assessing providers to ensure ongoing competency or to identify needs for refresher training [See [Quality Assessment Toolkit](#)].

FREQUENTLY REFERENCED INFORMATION

This section includes a table classifying appropriate circumcision methods according to the client’s age. While all three surgical methods are supported by PEPFAR, not all device-based methods are; providers using PEPFAR funding for device-based VMMC should understand the differences.

Table 5.1. VMMC Surgical and Device-Based Methods and Age Groups where Methods May be Used

CRITERIA	SURGICAL METHODS			VMMC DEVICES					
VMMC Method	Forceps-guided	Dorsal Slit	Sleeve Resection	Elastic collar compression (e.g. PrePex™)	Collar clamp (e.g. ShangRing)	Vice clamp (e.g. TaraKlamp™, Neo-alisklamp™)	Crush (e.g. Unicirc®)	Ligature compression (e.g. Circumplast®, Zhenxi Ring™)	CCSAC [Circular Cutter with Stapled Anastomosis for Circumcision (CCSAC)]
Appropriate Age Group	15+	10+	10+	13+	13+	Children 2+; Men 16-42	Pending WHO pre-qualification (Undergoing phase IV field trial in South Africa)	18+	Expensive; not yet evaluated by WHO
PEPFAR-supported for use	Yes	Yes	Yes	Yes	Yes	No	No	No	No

FOR ADDITIONAL INFORMATION

TRAINING BASICS

VMMC service providers must be competent in the skills required to provide the full package of medical circumcision and HIV prevention services outlined by WHO and endorsed by PEPFAR. Training curricula for clinicians providing circumcisions must focus on the knowledge and skills required not only to perform safe and **high-quality** circumcisions, but also on counseling basics so that clinicians can reinforce appropriate messaging when interacting with VMMC clients [See [VMMC Video: Implementing Best Practices](#), [WHO Manual for Male Circumcision Under Local Anaesthesia, 1st edition](#), [VMMC Global Health e-Learning Course: Male Circumcision: Policy & Programming](#), and [VMMC Counseling Training Package](#)].

In-service training programs for clinicians who will perform circumcisions are designed for trainees who have previously completed preservice training in basic surgical techniques, including circumcision. The same holds true for curricula for clinical/surgical assistants and counselors (ideally). The Ministry of Health (MOH) and/or Ministry of Defense must endorse clear training guidelines and competencies for VMMC staff, and staff must complete training and be deemed technically competent by trainers before beginning to provide VMMC for HIV prevention services. Training and certification of competency by an in-service training program is important after a credentialed clinician has completed his or her preservice training because the services provided in the context of the HIV prevention program encompass knowledge and skills beyond just the clinical/surgical techniques of foreskin removal, e.g., HIV testing and counseling, HIV risk reduction counseling in relation to circumcision, syndromic screening of STIs, PEPFAR policies about circumcision technique and client age, device-based techniques likely to be introduced after preservice training, commodities that may be unique to the HIV prevention program supply chain, and special considerations for HIV-positive clients.

The VMMC Online Training Hub

The USAID and PEPFAR-funded Strengthening High Impact Interventions for an AIDS-free Generation (AIDSFree) Project is in the process of developing an innovative training platform for VMMC providers. The VMMC Online Training Hub (OTH) standardizes curriculum content and ensures consistent delivery of course materials. The learning management system (LMS) will track providers' training dates, competency scores, strengths and weaknesses, and the time it takes them to complete the course. The LMS will also facilitate engagement with trainees to introduce new or updated information, confirm ongoing competencies, remediate weaknesses, and track post-training service delivery volumes. The OTH provides a blended learning approach with linkages to the clinical practicum, and will enable providers to train intermittently, repeatedly, and for durations that accommodate their schedules. It will allow trainers and program managers to customize training, so that personnel time is only directed to subjects relevant to an individual's current learning needs.

AIDSFree is working in collaboration with USAID, drawing on the technical knowledge of experts in the field to develop the OTH, and using PEPFAR and WHO guidelines and resources as source materials for curriculum development. The first eight modules of the curriculum are in progress. Usability testing of the OTH took place in South Africa in February 2017, and the project will apply lessons learned from these experiences as the modules are piloted in South Africa with in-country partners. To learn more about the OTH, please visit the AIDSFree website here: <https://aidsfree.usaid.gov/resources/vmmc-online-training-hub>.

Figure 5.1. Model of the VMMC Online Training Hub



Note: Clinicians participating in the VMMC for HIV prevention program should complete in-service training and be deemed competent by a government-recognized training partner, even if the clinician has previously completed preservice training.

TRAINING ON ELECTROCAUTERY

Use of electrocautery is becoming common in VMMC programs. Sites using this technology for hemostasis must ensure clinical staff are well trained in its use. While there are clear advantages to electrocautery, misuse may result in harm to clients. Site managers and providers should be well informed about all aspects of electrocautery detailed in the [Manual for Use of Electrocautery in VMMC](#). Key considerations are as follows:

- Channeling effect may occur if used on viscous tissue with narrow pedicle, e.g., penis, testes.
- Monopolar diathermy should not be used for infant circumcision because the point of maximal electrical resistance may be at the base of the penis, particularly if the penis is under any traction, with risk of coagulation and loss of the whole penis.
- Care has to be taken to ensure that the patient is not in contact with any metal or conducting material as there is a risk of earth leakage and burns at the point of contact with the conducting material. This risk is greatest with monopolar diathermy; but whenever diathermy is used, care must be taken in positioning patient on the operating table, the choice of operating tables, and clinic construction to prevent leakage of current to earth.
- The grounding plate should be placed so that there is a broad area of contact between the plate and the patient's skin. Sometimes it may be necessary to shave hairs to ensure good contact.

- If the machine fails to respond when the surgeon activates the current or there is no obvious and immediate visual evidence of coagulation, the surgeon should immediately stop applying the current and check all connections and the grounding plate. If the surgeon continues to apply current, burns may occur where resistance is greatest. This is most common where the grounding plate is in contact with the body or where the body is in contact with metal. In rare circumstances, the burn may occur elsewhere on the body.
- When using diathermy, the surgeon should apply the forceps as precisely as possible. The best results will be obtained if the blood vessel is between the diathermy prongs with minimal other tissue, and the current activated for the shortest time needed to ensure hemostasis. If too much tissue is grasped, diathermy will not stop the bleeding because the burn is too diffuse.
- Prolonged diathermy causing large black burns should be avoided as these may result in infection, increased postoperative pain, and scar tissue formation.
- Particular care must be taken near the frenulum because the urethra is near the surface, and there is a risk of creating a fistula by burning through to the urethra.
- Diathermy should also be used with caution close to the skin and mucosal edges as transmitted heat may cause burns to the skin or the wound edges, which may affect healing. Diathermy can be used to stop bleeding from small blood vessels, but for larger vessels, it is safer to apply an artery forceps and tie or under-run.

SUPPORTIVE SUPERVISION TRAINING

Supervisors of VMMC providers and staff at VMMC sites should also receive training. For sustainability and integration of a VMMC program within the health system, the 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” (Marquez and Kean 2002 p. 12). The [WHO Manual for Male Circumcision Under Local Anaesthesia, 1st edition](#) includes tools used to assess providers before, during, and after service provision. In addition, a variety of performance improvement and quality assessment (QA) materials have been developed that supervisors can use during their supportive supervision [See [Quality Assessment Toolkit](#)]. Supervisors who were previously trained in supportive supervision need only the VMMC technical training, whereas supervisors who have received VMMC technical training may need only supportive supervision training [See [Supervising Health Care Services: Improving the Performance of People](#)].

KEY CONSIDERATIONS FOR TRAINING

- In terms of timing and selection of trainees, it is important to schedule training immediately before selected staff will begin performing VMMC. This is critical to ensure that medical professionals retain the skills acquired in training and that training resources are used efficiently. Lapses of time between the completion of training and actual service delivery may compromise retention of knowledge and skills gained during training.
- Clinical staff on a rotation schedule 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 supported in a multipurpose health care facility with many staff members, such as a hospital, it is best to establish a memorandum of understanding (MOU) with the host facility regarding VMMC training standards to ensure that only those completing the government recognized in-service VMMC for HIV prevention training provide VMMC services.
- All VMMC training must include in its curriculum the use of emergency supplies to manage particularly severe complications. Every person working in a clinical role at the VMMC site should be adequately trained in emergency management, including resuscitation, and in the use of the supplies and equipment provided for this purpose.
- 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 [Chapter 12](#)].
- It is important to keep an accurate record 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 [Training Information Management System Form](#)].

CASE STUDIES

[Case Study 5.1. New VMMC Training Modality Reduces Training Time for Private Providers in Namibia](#)

[Case Study 5.2. Integration of Pre-Campaign Clinical Refresher Training to Ensure Service Quality in Malawi](#)

TOOLS, INSTRUMENTS & GUIDANCE DOCUMENTS

The following documents, which are available online and in the accompanying external media (included with the hard copy version of this Guide), provide the background information or procedural guidance used for development of this chapter.

1. [WHO Manual for Male Circumcision Under Local Anaesthesia, 1st edition](#)
2. [COSECSA/PSI VMMC AE Action Guide](#)
3. [Manual for Use of Electrocautery in VMMC](#)
4. [VMMC Counseling Training Package](#)
5. [VMMC Video: Implementing Best Practices](#)
6. [Global Health e-Learning Course—Male Circumcision: Policy & Programming](#)
7. [Supervising Healthcare Services: Improving the Performance of People](#)

8. [VMMC Standardized Job Descriptions](#)
9. [Training Information Management System Form](#)
10. [Quality Assessment Toolkit](#)

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ABBREVIATIONS

AE	adverse event
HIV	human immunodeficiency virus
M&E	monitoring and evaluation
MOH	Ministry of Health
MOU	memorandum of understanding
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
QA	quality assessment
STI	sexually transmitted infection
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	United States Agency for International Development
VMMC	voluntary medical male circumcision
WHO	World Health Organization

CASE STUDY 5.1.

New VMMC Training Modality Reduces Training Time for Private Providers in Namibia

Most private for-profit health care providers are running independent clinics that depend entirely on availability and effort of staff to generate income. Therefore it is a challenge to get the providers to attend trainings, as they are frequently working in their practices. Learning sessions targeting private providers are often run in the evening or on weekends to accommodate their schedules. Although short sessions of one to two hours, evenings or weekends, may be suitable, it poses a challenge when more time is required for longer trainings. The national VMMC training is conducted over two weeks, making it logistically impossible to get private providers to attend.

To overcome these challenges, a novel training modality was used, comprising a four-phase approach:

- All private providers in Namibia were medical doctors who were already practicing male circumcision. This process identified their training needs to help the trainers tailor the training accordingly.
- Online modules were provided so that clinicians could access content when convenient.
- One and a half days of in-person training was used to deliver key concepts and information on VMMC.
- An all-day supervised clinical skills orientation session was conducted.

Figure 5.1.1. Provider trainee conducting clinical skills orientation session under supervision of a trainer.



Starting in May 2015 more than 30 private providers who completed online modules have received the short one and half day trainings in three groups of 10–15 providers. This was followed by a one-day intensive clinical practice session and post-training evaluation.

Given that most of the providers had some level of familiarity with providing male circumcision, the overarching goal of the skills training was to standardize the way the procedure is performed. The all-day clinical session had an added bonus of physicians from different sites interacting, building on each other's confidence and exchanging ideas. The timing of the face-to-face and clinical practice was crucial: Health seeking habits vary significantly within a month, and aligning the trainings with the low volume of patients on weekends presented an attractive option for providers. This approach would work very well in both private and public settings.



CASE STUDY 5.2.

Integration of Pre-Campaign Clinical Refresher Training to Ensure Service Quality in Malawi

To implement a six-week major campaign from July to September 2015 in the Thyolo, Chikwawa, and Zomba districts of Malawi, Jhpiego's USAID-funded Sankhani Moyenela Program and the District Health Offices needed a large number of additional staff (clinicians, monitoring and evaluation [M&E], drivers, counselors, etc.) to meet ambitious program targets. The Ministry of Health (MOH) at the national level and from various districts countrywide provided the additional staff. Although trained in VMMC, most of the 120 additional providers were not routinely providing VMMC in their home districts. To ensure quality service delivery, the Sankhani Moyenela Program arranged a two-day, pre-campaign orientation for all campaign staff. The first day was dedicated to general issues of quality, the campaign strategy, and logistics. The second day focused on job- and task-specific skills orientation and functions.

For clinicians, the refresher training included in-depth discussions about quality shortcomings, clinical simulation, and practice sessions focused on technical areas. While the orientation broadly focused on ensuring a thorough understanding of the minimum package of services, specific focal areas included the dorsal slit technique, injection of anesthesia, hemostasis, and infection prevention, among other aspects that had been identified as gaps during continuous quality assurance activities. During this orientation and refresher training, activity supervisors also facilitated a case-by-case audit of severe adverse events (AEs) from previous VMMC campaigns. The audit was designed to heighten team vigilance about prevention of AEs and to highlight critical gaps for detailed discussion and practice during the orientation.

The clinical skills refresher training was an essential aspect of the pre-campaign staff orientation. The tailored sessions allowed the trainers to identify and address quality gaps to ensure that the 24 clinical teams were sufficiently prepared to provide safe VMMC services to more than 17,500 clients over the six-week period. In total more than 100 clinical staff were trained, and the AE rate during the campaign was <0.5% (n = 48: 6 severe and 42 moderate), which was an improvement from previous campaigns. Furthermore, the refresher training helped clinical managers to distribute staff within teams to account for observed skills and experience. The exercise also allowed clinical managers to identify individuals who would need extra support, enabling them to more effectively target supportive supervision and mentoring visits during the course of the campaign.

CHAPTER 6.

Providing the VMMC Minimum Package of Services

GOALS

To ensure site staff are able to:

- Provide clients with all components of the VMMC service package, in accordance with national, World Health Organization (WHO) and U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) recommendations.
- Provide VMMC services that are compliant with PEPFAR policies.

WHAT USERS NEED TO KNOW

WHO recommends that all clients receiving VMMC service receive a comprehensive package of services to support HIV/STI prevention or care and safe recovery [See [WHO Manual for Male Circumcision Under Local Anaesthesia, 1st edition](#) and [PEPFAR Technical Considerations for COP/ROP 2016](#)]. The “minimum package of services” (see Figure 6.1)—which should be available to all VMMC clients at all sites—includes: 1) optional HIV testing and counseling services for all male clients and, where possible, their partners; 2) active referral of clients determined to be HIV-positive to HIV care and treatment programs, including determination of successful linkage 3) age-appropriate sexual risk reduction counseling, including recommendations for abstinence during wound healing; pre-procedure clinical screening (focused physical exam and medical history) to detect sexually transmitted infections (STI) and contraindications to circumcision; 4) screening and treatment of STIs; 5) circumcision by a medical method approved by WHO; 6) post-procedure follow-up, including systematic assessment of adverse events and, 7) provision and promotion of correct and consistent use of condoms, preferably both male and female condoms.

To ensure high quality VMMC services, the VMMC team in general and providers in particular must be competent in assessing clients for VMMC eligibility including evaluation of clients for tetanus immunity or vaccination against tetanus in countries where it is appropriate [See [WHO Guidelines on Tetanus and VMMC July 2015](#) and [September 2016](#)] use of at least one WHO-approved VMMC method; anesthetic dosing (by use of weight based dosing anesthetic charts or calculation of an appropriate minimum dose) and adequate infection control practices [See [Chapter 9](#)]. This chapter describes the WHO comprehensive package of services including what providers need to consider as they attend to VMMC clients from client screening, through the procedure, recovery and follow up.

FREQUENTLY REFERENCED INFORMATION

Figure 1.1. WHO/UNAIDS Recommendations WHO Minimum Package of VMMC Services



HIV TESTING SERVICES

The recommendation for and offer of onsite HIV testing services (HTS) [See [Guidance on Provider-Initiated HIV Testing and Counseling \(PITC\) in Health Facilities](#)]: Clients declining HIV testing during VMMC services should be informed of alternative sources of HTS at the VMMC site (if static site) and other sites where such services may be obtained. However, clients should never be denied VMMC because they decline HIV testing or based on the results of their tests.

VMMC represents a rare and valuable opportunity to provide HIV testing services (HTS) to men and if necessary to link them to HIV care and treatment [see below]. HTS 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 HTS facilities are referring eligible clients to VMMC services.

As part of the WHO-recommended minimum package of services, PITC (provider-initiated HIV testing and counseling) should be offered as part of the VMMC program [See [Guidance on Provider-Initiated HIV Testing and Counseling \(PITC\) in Health Facilities](#)]. Implementers should adhere to WHO guidance on PITC, including the minimum standards of pre-test information, informed consent post-test counseling based on serostatus, maintaining confidentiality, and use of point-of-care rapid HIV testing algorithms, as appropriate [See [Chapter 12](#)]. It is also critical to ensure that clients understand that while recommended, HIV testing is not required to access VMMC services. 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 (quality assurance) 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 (see [Chapter 10](#)).

REFERRAL TO HIV AND AIDS CARE AND TREATMENT:

Active linkage of HIV-positive clients identified at VMMC sites to HIV care and treatment programs. As part of the VMMC program, men who test HIV-positive 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 for minor surgery

(i.e., a CD4 of at least 350 and not in WHO clinical cancer stage III or IV), VMMC should be made available to him. It is important for HIV-positive men to be counseled about the increased risk of transmission to female partners if they resume sex before full healing. Records of referred clients should be maintained at site.

EDUCATION AND COUNSELING

Age-appropriate sexual risk-reduction counseling, including recommendations for abstinence during wound healing, information provided through group and individualized sessions about the benefits and risks of VMMC, and sexual and reproductive health education including healthy male norms and gender-based violence. [See [Counseling Resource Guide](#)]. When men seek VMMC services, it provides an ideal opportunity to address several important aspects of sexual and reproductive health needs. 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. **Targeted counseling for clients testing HIV-positive or declining HIV testing on the increased risk of HIV transmission to female partners if they resume sex before full healing should also be addressed.** As part of the VMMC program services, men who test HIV-negative should be counseled and given specific information about how to protect themselves from HIV infection besides just circumcision.

SEXUALLY TRANSMITTED INFECTION (STI) SERVICES

Syndromic screening for STIs prior to VMMC and treatment for those diagnosed [See [Guidelines for the Management of Sexually Transmitted Infections \(STIs\)](#)]. 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. Special packages should be planned for HIV-negative males, preferably through demand and communication approaches to ensure these men remain uninfected [See [Chapter 4](#)].

MALE CIRCUMCISION AND RELATED CLINICAL CARE

Circumcision should be provided by a method approved by WHO, and pre- and post-procedure care should be provided that meet the accepted standards of care for conventional circumcision surgery under local anesthesia [See [WHO Manual for Male Circumcision Under Local Anaesthesia, 1st edition](#)], PrePex [See [PrePex Instructions for Use](#)], and ShangRing [See: [ShangRing Instructions for Use](#)]. To ensure client safety and high quality services, the following should be considered for each client before, during and following circumcision.

- **VMMC eligibility assessment:** All clients seeking circumcision should undergo appropriate screening before they receive circumcision to reduce adverse events and to ensure a good outcome of circumcision. Eligibility for VMMC includes i) Provision of a signed informed consent or parental consent/assent and its documentation on the clients' file. ii) Documentation of the client's age. This helps to determine an age appropriate VMMC method; iii) ensuring proper screening through history and examination to document contra-indications (high blood pressure, diabetes, prolonged bleeding, etc) and indications of circumcision (phimosis, paraphimosis, genital warts, epispadias and hypospadias) and/or indications of surgery in general that may require the services of a specialist doctor or a higher medical center.

- **Circumcision methods:** Providers should use age-appropriate, WHO approved VMMC methods. Although three conventional surgical methods (Sleeve resection, Forceps guided, Dorsal slit) are currently approved, and can be used, the dorsal slit method is specifically recommended for boys 10-14. Since the release of the first edition of the “PEPFAR’s Best Practices for VMMC Site Operations: A Service Guide for Site Operations”, two medical circumcision devices which provide alternatives to the conventional surgical procedures have obtained WHO prequalification: PrePex in 2013 [See [WHO Prequalification PrePex Abstract](#)] and ShangRing in 2015 [See [WHO Prequalification ShangRing Abstract](#)]. In 2013, WHO also issued guidelines and considerations to assist national VMMC programs in their decision-making regarding the use of devices in VMMC scale-up strategies. [See [Use of Devices for Adult Male Circumcision for HIV Prevention in East and Southern Africa](#)].
- **Competency of providers and their assistants:** Circumcision providers should be well qualified, trained and certified to provide at least one of the VMMC methods approved by WHO. The assistants to providers should also receive appropriate training and be in position to give full support to the circumcision team, including in emergency management [See [Chapter 5](#)]. The surgical team should be competent to observe and maintain adequate IPC processes including clean OR, cleaning hands, waste segregation and disposal, surgical site prep, and use of sterile materials.
- **Tetanus risk mitigation in VMMC programs:** Beginning in 2014, issues of tetanus risk among VMMC clients and strategies to mitigate this risk have garnered increased attention. WHO convened experts to provide recommendations to national programs in defining tetanus risk mitigation strategies, including the clean care approach and options for vaccination. [See [Technical Consultation Update to the WHO March 2015 Meeting — WHO Informal Consultation on Tetanus and Voluntary Medical Male Circumcision](#) and [Technical Consultation Update to the WHO March 2015 Meeting and Tetanus and VMMC: Risk According to Circumcision Method and Risk Mitigation](#)]. Clients must receive written instructions on recommended post-procedure wound care that explicitly address the risk of wound infection and specifically tetanus risk mitigation including the danger of using traditional remedies for wound care. Written informed consent must be retained for clients or parental/guardian consent for minor clients. Additional information about tetanus risk and mitigation in VMMC programs can also be found in other chapters through this second edition of *PEPFAR’s Best Practices for VMMC Site Operations: A Service Guide for Site Operations*.
- **Post-procedure follow-up:** This includes systematic assessment and management of adverse events (AEs). [See [Chapter 7](#)].

MALE AND FEMALE CONDOMS

Promotion, demonstration, and onsite provision of condoms. Personnel at all sites providing VMMC for HIV prevention services with PEPFAR support should have a thorough understanding of the current VMMC Technical Considerations prepared annually as part of Country Operational Plan (COP) Guidance. [See: [PEPFAR VMMC Technical Considerations 2016](#) and [PEPFAR Country/Regional Operational Plan \(COP/ROP\) Guidance 2017](#).] The Technical Considerations summarize the PEPFAR VMMC Technical Working Group’s (TWG) additional recommendations for program implementation, as well as the policy-level requirements in effect as a condition of receiving PEPFAR VMMC funding.

PEPFAR POLICY GUIDANCE DIRECTIVES FOR VMMC

Excerpted VMMC Technical Considerations, PEPFAR Country/Regional Operational Plan (COP/ROP) Guidance 2017

“Voluntary Medical Male Circumcision (VMMC) VMMC reduces the risk of heterosexual HIV acquisition for men by at least 60 percent and helps to break the cycle of transmission to future sexual partners as the preventive effect remains strong throughout aging. To have the most impact, VMMC programs should be implemented in scale-up districts with a high HIV burden and low coverage of male circumcision services in the fourteen priority countries (Botswana, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Namibia, Rwanda, South Africa, Swaziland, Tanzania, Uganda, Zambia, and Zimbabwe).

In COP17, programs should continue to prioritize clients aged 15–29 years, especially those at high risk such as STI clients and partners in serodiscordant couples, for immediate impact. As prioritized areas approach saturation in this population group (e.g., 80% or more among males 15–29 years in select geographic areas are circumcised), programs are urged to extend the prevention benefit to adolescent boys 10–14 years of age and to begin policy discussions with governments about neonatal circumcision. Teams must also ensure that PEPFAR-supported VMMC programs include the WHO-recommended minimum package of accompanying services, including the offer of HIV testing, risk reduction counseling, condoms, and STI screening and treatment or referral. HIV testing services should be offered only on request, and not routinely, to boys and adolescents who have not yet had sexual debut, given low rates of HIV infection in these populations. In addition, WHO recommendations on tetanus immunization and the clean care approach for all circumcisions must be followed.”

Rare tetanus cases in VMMC clients have been reported; WHO has issued a meeting report on an informal consultation regarding tetanus mitigation in service delivery and communication with clients. [See [Tetanus and Voluntary Medical Male Circumcision: Risk According to Circumcision Method and Risk Mitigation Report of the WHO Technical Advisory Group on Innovations in Male Circumcision—Consultative Review of Additional Information, 12 August 2016](#)]. PEPFAR programs should support Ministries of Health/Defense as they implement the recommendations outlined by WHO. Immediate reporting of any death or notifiable adverse event is required per the 2015 PEPFAR Reporting Protocol for VMMC Client Death and Notifiable Adverse Events. Implementing partners should check with their funding agency to ensure they have the current version of the protocol, since it is subject to updates.

Implementing mechanisms funded to support VMMC program implementing must fully comply with the following policy directives. All programs must put systems in place to monitor and report VMMC indicators and required disaggregations and to document coverage trends in scale-up SNUs [subnational units] and age groups. Geographic prioritization of VMMC should focus on (1) DREAMS [Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe (Women) Project] districts, and (2) non-DREAMS scale-up districts (with high HIV burden and low male circumcision prevalence). The priority age group for VMMC is males 15–29 years of age. Programs should ensure external quality assessment and continuous quality improvement activities are routinely conducted. VMMC should not be withheld from healthy HIV-positive males, but they should receive appropriate counseling so that they understand that male circumcision (MC) is not known to lower their risk of transmitting HIV to their sexual partners and will not reverse their own HIV status, and that resuming unprotected sex prior to full wound healing will increase the risk of transmission. However, no males should be required to test for HIV in order to access VMMC. Programs should confirm that any male testing HIV-positive is linked to care

and treatment services. Any reimbursement to clients for travel and any rewards to teams of mobilizers to increase uptake of VMMC should be carefully evaluated to assure there is no one-for-one remuneration for VMMCs performed, and no actual or perceived coercion of clients.

Programs should plan for timely procurement and distribution of VMMC commodities and equipment including: pharmaceuticals, surgical instruments, devices, consumables and medical and waste management supplies. Programs can use PEPFAR funds to procure WHO pre-qualified devices and use them in routine service delivery, following WHO guidance. Currently, ShangRing and PrePex devices are pre-qualified for ages >13 years. Additionally, pre-qualified sizes must be used.

One issue noted during COP and POART [PEPFAR Oversight Accountability Response Team] reviews was that many programs continue to see a high proportion of VMMC procedures in 10-14 year olds rather than 15-29 years old. Programs should prioritize clients aged 15–29 years of age for immediate impact and make sure that the focus is to reach 80% coverage among that group in a very short period of time. Once an SNU has reached 60% coverage in the 15–29 year age groups, the prioritization of clients aged 10–14 years can increase.

WEIGHT-BASED DOSING OF LOCAL ANESTHETIC AGENTS

(Excerpted from [Adverse Event Action Guide for VMMC by Surgery or Device, 1st Edition, 2016](#))

Table 6.1. Starting and Maximum Doses of 2.0% Lidocaine (Lignocaine) without Bupivacaine, by Volume

Safe Local Anesthetic Dosing—Starting* and Maximum** Values		
2% LIDOCAINE		
Weight in kg	Starting Volume	Maximum Safe Volume
20–29 kg***	2 ml	Additional 1 ml to TOTAL of 3 ml
30–39 kg***	3 ml	Additional 1 ml to TOTAL of 4 ml
40–50 kg	4 ml	Additional 2 ml to TOTAL of 6 ml
More than 50 kg	5 ml	Additional 2 ml to TOTAL of 7 ml

*Starting dose lidocaine (lignocaine) 2 mg/kg.

**Maximum safe dose lidocaine 3 mg/kg.

***Use 5 ml syringe so that volumes can be measured accurately.

Starting volume usually adequate; increase up to **maximum** volume (dose) only if required for pain control up to the **maximum**.

Table 6.2. Starting and Maximum Doses of 2.0% Lidocaine (Lignocaine) with Bupivacaine, by Volume

If bupivacaine is to be used with lignocaine 2.0%, use concentration of 0.5% with 1:1 combination.

Safe Local Anesthetic Dosing—Starting* and Maximum** Values		
MIXTURE OF 2% LIDOCAINE AND 0.5% BUPIVACAINE (1:1 MIXTURE; EQUAL VOLUMES OF EACH)		
Weight in kg	Starting Volume (1:1 mixture)	Maximum Safe Volume (1:1 mixture)
20–29 kg***	1 ml of each (2 ml total)	Additional 1 ml of each drug to TOTAL of 4 ml (maximum 2 ml of each)
30–39 kg***	2 ml of each (4 ml total)	Additional 1 ml of each drug to TOTAL of 6 ml (maximum 3 ml of each)
40–50 kg	3 ml of each (6 ml total)	Additional 1 ml of each drug to TOTAL of 8 ml (maximum 4 ml of each)
More than 50 kg	4 ml of each (8 ml total)	Additional 1 ml of each drug to TOTAL of 10 ml (maximum 5 ml of each)

*Starting dose lidocaine 1 (lignocaine) .5 mg/kg / bupivacaine 0.3 mg/kg

**Maximum safe dose lidocaine 2.0 mg/kg / bupivacaine 0.5 mg/kg

***Use 5 ml or smaller syringe so that volumes can be measured accurately

Starting volume usually adequate; increase up to **maximum** volume (dose) only if required for pain control up to the **maximum**.

Table 6.3. Starting and Maximum Doses of 1.0% Lidocaine without Bupivacaine, by Volume

Safe Local Anesthetic Dosing—Starting* and Maximum** Values		
1% LIDOCAINE		
Weight in kg	Starting Volume	Maximum Safe Volume
20–29 kg***	4 ml	Additional 2 ml to TOTAL of 6 ml
30–39 kg	6 ml	Additional 3 ml to TOTAL of 9 ml
40–50 kg	8 ml	Additional 4 ml to TOTAL of 12 ml
More than 50 kg	10 ml	Additional 5 ml to TOTAL of 15 ml

*Starting dose lidocaine (lignocaine) 2 mg/kg

**Maximum safe dose lidocaine 3 mg/kg

***For those weighing less than 30 kg, use 5ml syringe so that volumes can be measured accurately Starting volume usually adequate; increase up to **maximum** volume (dose) only if required for pain control up to the **maximum**.

Table 6.4. Starting and Maximum Doses of 1.0% Lidocaine (Lignocaine) with Bupivacaine, by Volume

If bupivacaine is to be used with lignocaine 2.0%, use concentration of 0.25% with 1:1 combination.

Safe Local Anesthetic Dosing—Starting* and Maximum** Values		
MIXTURE OF .5% LIDOCAINE AND 0.25% BUPIVACAINE (1:1 MIXTURE; EQUAL VOLUMES OF EACH)		
Weight in kg	Starting Volume (1:1 mixture)	Maximum Safe Volume (1:1 mixture)
20–29 kg***	3 ml of each (6 ml total)	Additional 1 ml of each drug to TOTAL of 8 ml (maximum 4 ml of each)
30–39 kg***	4 ml of each (8 ml total)	Additional 2 ml of each drug to TOTAL of 12 ml (maximum 6 ml of each)
40–50 kg	5 ml of each (10 ml total)	Additional 3 ml of each drug to TOTAL of 16 ml (maximum 8 ml of each)
More than 50 kg	5 ml of each (10 ml total)	Additional 5 ml of each drug to TOTAL of 20 ml (maximum 10 ml of each)

*Starting dose lidocaine (lignocaine) 1.5 mg/kg/bupivacaine 0.3 mg/kg

**Maximum safe dose lidocaine 2.0 mg/kg/bupivacaine 0.5 mg/kg

Starting volume usually adequate; increase up to **maximum** volume (dose) only if required for pain control up to the **maximum**.

To improve provider efficiency through minimizing numbers of syringes needed, starting doses have been kept at or below 10 ml and maximum doses at or below 20 ml.

FOR ADDITIONAL INFORMATION

Suggested Staffing Roles for VMMC Programs: See [Chapter 5](#) on staff training.

CASE STUDIES

[Case Study 6.1. Improving Active Referral and Linkages to HIV Care and Treatment Services for HIV-Infected Men Identified through VMMC Services in Lesotho](#)

TOOLS, INSTRUMENTS & GUIDANCE DOCUMENTS

The following documents, which are available online and in the accompanying external media (included with the hard copy version of this Guide), provide the background information or procedural guidance used for development of this chapter.

1. [WHO Manual for Male Circumcision Under Local Anaesthesia, 1st edition](#)
2. [PEPFAR Technical Considerations for COP/ROP 2016](#)
3. [Guidance on Provider-Initiated Testing and Counseling in Health Facilities](#)
4. [VMMC In-Service Communication: Best Practices Guide](#)
5. [Guidelines for the Management of Sexually Transmitted Infections \(STIs\)](#)
6. [PrePex Instructions for Use](#)
7. [ShangRing Instructions for Use](#)
8. [PEPFAR Country/Regional Operational Plan \(COP/ROP\) Guidance 2017](#)
9. [WHO PQ PrePex Abstract](#)
10. [WHO PQ ShangRing Abstract](#)
11. [Use of Devices for Adult Male Circumcision for HIV Prevention in East and Southern Africa](#)
12. [Technical Consultation Update to the WHO March 2015 Meeting—WHO Informal Consultation on Tetanus and Voluntary Medical Male Circumcision](#)
13. **2015 PEPFAR Reporting Protocol for VMMC Client Death and Notifiable Adverse Events:** Can be obtained by contacting in-country USAID Mission staff.

REFERENCES

- Lesotho Ministry of Health and Social Welfare. 2009. *Lesotho Demographic and Health Survey, 2009*. Maseru, Lesotho and Calverton, Maryland, USA: ICF Macro. Available online at: <http://dhsprogram.com/pubs/pdf/FR241/FR241.pdf>.
- Population Services International and College of Surgeons of East, Central, and Southern Africa. 2016. *Adverse Event Action Guide for Voluntary Medical Male Circumcision by Surgery or Device, 1st ed.* Available online at: <https://www.malecircumcision.org/resource-bundle/adverse-event-guide>.

ABBREVIATIONS

AE	adverse event
ART	antiretroviral therapy
COP	Country Operational Plan
DREAMS	Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe (Women) Project
GIS	geographic information systems
HIV	human immunodeficiency virus
HTC	HIV testing and counseling
HTS	HIV testing services
MC	male circumcision
PEPFAR TWG	Technical Working Group
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PITC	Provider-Initiated HIV Testing and Counseling (PITC)
RHSP	Rakai Health Sciences Program
SNU	subnational units
STI	sexually transmitted infection
STI	sexually transmitted infection
VMMC	voluntary medical male circumcision
WHO	World Health Organization



CASE STUDY 6.I.

Improving Active Referral and Linkages to HIV Care and Treatment Services for HIV-Infected Men Identified through VMMC Services in Lesotho

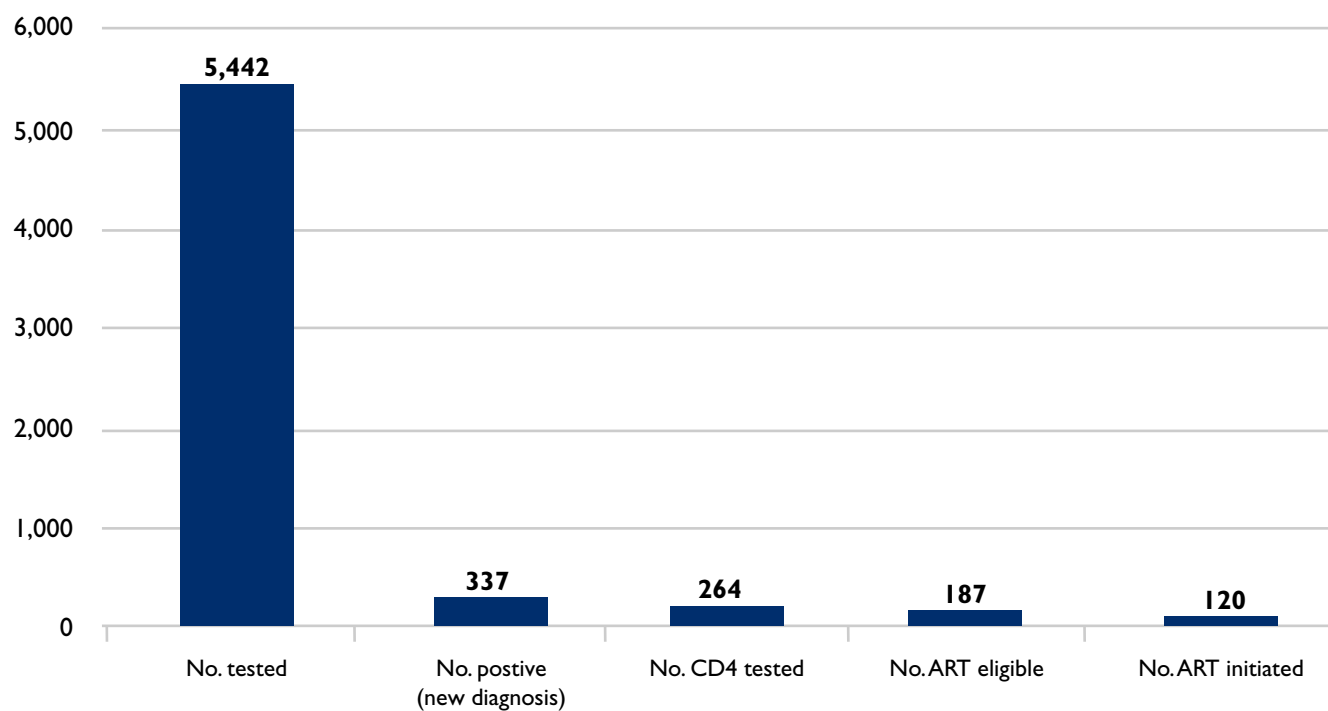
The World Health Organization (WHO) now recommends that any individual infected with HIV should begin antiretroviral treatment (ART) as soon as possible after diagnosis, irrespective of CD4 count. This expanded use of ART is called *Test and Start*; it is supported by clinical trial findings confirming that early use of ART helps people living with HIV live longer and stay healthier while reducing their risk of transmitting the virus to partners.

The critical first step in the HIV continuum of care is diagnosis of infection through HIV testing services (HTS). In Lesotho, uptake of HTS among men increased with scale-up of voluntary medical male circumcision (VMMC) services. Of the more than 100,000 males circumcised, more than 80 percent received HTS at the VMMC sites, which is impressive especially considering that fewer than 40 percent of men had ever tested prior to the start of the VMMC program (DHS 2009).

With PEPFAR funding through USAID, Jhpiego supported the Lesotho Ministry of Health to scale up VMMC services. To ensure that HIV-positive clients identified at VMMC sites were enrolled into HIV care and treatment services, active referral and linkages were introduced by the Lesotho VMMC program at two pilot sites in 2013 and expanded to all VMMC sites the following year. All clients testing HIV-positive received point-of-care CD4 testing and were offered the option of receiving HIV care and treatment at the same private clinic where they were circumcised. Clients also received information about additional HIV clinics where they would start ART, such as public facilities or specialized ART centers run by the AIDS Healthcare Foundation.

From October 2013 to August 2015, the period following the introduction of the active linkages for HIV-infected clients, 6,540 men were circumcised, and of those, 5,442 (83%) tested for HIV. Of these testers, 568 (8.6%) were HIV-positive, including 337 (59%) newly diagnosed at the 2 VMMC sites. Of those newly diagnosed, 264 (78%) had a CD4 count documented; 187 (70%) were ART-eligible and 120 (64%) initiated and were confirmed to be on ART within a month of diagnosis.

Figure 6.1.1. Cascade of HIV Linkage at Jhpiego Clinics in Lesotho



From this review, two key lessons can be noted. First, VMMC services can increase HTS uptake among men and contribute to the identification of HIV-infected men and young male adolescents. Second, active and closely monitored referrals of HIV-positive clients to care and treatment services will facilitate timely initiation of ART.





CHAPTER 7.

Managing, Monitoring, and Reporting VMMC Adverse Events

CHAPTER GOALS

Ensuring that staff providing voluntary medical male circumcision (VMMC) in sites supported by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) can:

- Screen for, diagnose, and document adverse events (AEs) during and after VMMC surgery
- Manage clinical AEs
- Provide appropriate referrals when AEs occur.

WHAT USERS NEED TO KNOW

To ensure the safety and quality of VMMC service provision, sites or implementing partners must:

- Have all essential commodities for managing AEs and (if needed) referring clients for management of the most severe AEs.
- Have sufficient staff trained to provide VMMC services and use VMMC commodities, including equipment for managing AEs. U.S. Government agencies or implementing partners should provide annual assessment of VMMC site readiness.

To ensure the safety and quality of VMMC services, clinical providers must:

- Screen all VMMC clients for complications during surgery, before discharge, or at follow-up. [See [WHO Manual for Male Circumcision Under Local Anaesthesia, 1st edition](#)].
- Communicate in language appropriate for a layperson to be sure that each client understands the VMMC procedure, post-surgical care, and possible post-surgical problems that may need treatment, and how to obtain treatment. [See [VMMC In-Service Communication: Best Practices Guide](#)].
- Know how to diagnose and manage for AEs. [See [Adverse Event Action Guide for Voluntary Medical Male Circumcision by Surgery or Device, 1st Edition, 2016](#)].
- Document AEs according to type and severity ([Table 7.1](#)), and report them to the Ministry of Health and funding agency field office.
- *Immediately report the most severe AEs to the Ministry of Health and the Office of the Global AIDS Coordinator (OGAC).* [See [PEPFAR Reporting Protocol for VMMC Client Death and Notifiable Adverse Events, Form 1](#)]. Implementing partners should check with their funding agency to ensure they have the current

version of the protocol, since it is subject to updates. These six events are rare, but require immediate notification if they occur within 30 days of circumcision: 1) death; 2) partial or complete amputation of the glans or shaft; 3) tetanus (nonfatal); 4) any AE resulting in permanent disability (probable or definite); 5) any AE resulting in permanent anatomic deformity (probable or definite); and 6) any AE resulting in hospitalization > 3 days. Staff should begin the reporting process for any of these events the same day they learn of them.

Figure 7.1. Six Adverse Events Subject to Immediate Notification Requirements (If Any Occurs During or Within 30 Days of Circumcision)

1. Death
2. Partial or complete amputation of the glans or shaft
3. Tetanus
4. Any adverse event resulting in permanent disability (definite or probable)
5. Any adverse events resulting in permanent anatomic deformity (definite or probable)
6. Any adverse event resulting in hospitalization > 3 days.

- Site staff should use this form [see [PEPFAR Reporting Protocol for VMMC Client Death and Notifiable Adverse Events, Form 1](#)] to initiate the reporting process on the same day that they become aware of any of the six events listed above. Implementing partners should check with their funding agency to ensure they have the current version of the protocol, since it is subject to updates.

Note: Tetanus cases have been identified following VMMC. The World Health Organization (WHO) issued updated information to national VMMC programs to help mitigate tetanus risk. [See [Tetanus and Voluntary Medical Male Circumcision: Risk According to Circumcision Method and Risk Mitigation, Report of the WHO Technical Advisory Group, 12 August 2016](#)]. Additionally, PEPFAR provided a resource to enable site-level staff to translate national policies on tetanus vaccination and risk mitigation into practice. [See [Considerations for PEPFAR-Supported VMMC Programs Incorporating Tetanus Vaccination and Other Risk Mitigation Activities](#)].

FREQUENTLY REFERENCED INFORMATION

This section includes a table classifying VMMC adverse events by severity; provides details on the basic principles outlined above; and gives information on additional considerations for VMMC sites and programs.

Table 7.1. VMMC Adverse Event Definitions and Severity Classification, adapted from *Adverse Event Action Guide for Voluntary Medical Male Circumcision by Surgery or Device, 1st Edition, 2016*

Adverse Event Classifications and Definitions: During Surgery or Prior to Discharge from VMMC Clinic, or During Device Placement or Wearing			
ADVERSE EVENT	MILD	MODERATE	SEVERE
AN: ANESTHETIC-RELATED PROBLEM			
Surgery and Device	Mild localized allergic reaction at injection site without swelling and systemic reaction.	Symptoms of reaction to anesthetic include light-headedness, nervousness, or dizziness. These symptoms may resolve on their own and are not so severe as to necessitate use of emergency commodities, such as medicines or equipment from the emergency cart/kit. These symptoms do not require transfer to another facility or admission to the hospital.	Symptoms of severe systemic allergic reaction to local anesthetic including rash, urticaria, angioedema, and shortness of breath, or symptoms of overdose of local anesthetic including light-headedness, nervousness, confusion, dizziness, drowsiness, ringing of ears, blurred or double vision, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression, bradycardia, or hypotension requiring use of medicines or equipment from the emergency cart/kit/list of emergency commodities or hospitalization to manage.
BL: BLEEDING			
Surgery	Intra-operative bleeding that is more significant than usual or post-operative spotting of the bandage with blood; both easily controlled.	Intra-operative bleeding or bleeding that occurs prior to discharge that requires a pressure dressing to control, or that requires additional skin sutures without surgical re-exploration of the wound.	Intra-operative bleeding requiring blood transfusion, transfer to another facility, or hospitalization; or post-operative bleeding that requires surgical re-exploration, hospitalization, or transfer to another facility.
ADVERSE EVENT	MILD	MODERATE	SEVERE

Device	Bleeding during placement or wearing that is more significant than usual or spotting of the bandage or clothing with blood; both easily controlled.	Bleeding during placement or wearing that requires a pressure dressing to control without surgical re-exploration of the wound or removal of the device.	Bleeding during placement or wearing that requires blood transfusion, transfer to another facility, or hospitalization; or bleeding that requires surgical exploration, removal of device, placement of sutures, hospitalization, or transfer to another facility.
PA: PAIN			
Surgery	Client expresses discomfort, however is able to remain still and cooperate for the procedure. No additional local anesthetic is required.	Pain requiring additional local anesthesia.	Pain not responsive to additional local anesthesia.
Device	Client expresses discomfort, however is able to remain still and cooperate for the procedure.	Client expresses discomfort and is not able to cooperate well with procedure. For programs that utilize a visual analogue scale (VAS) for rating severity, a VAS score of 5-7 (on a 1-10 scale).	Client rates pain as very severe. For programs that utilize a visual analogue scale (VAS) for rating severity, a VAS score of 8-10 (on a 1-10 scale).
SD: SCARRING/DISFIGUREMENT/POOR COSMETIC RESULT; EXCESS SKIN REMOVAL; INJURY TO PENIS			
Surgery	<p><i>Excess skin removal</i>—Tightness of skin discernible but additional sutures or mobilization of skin not needed for skin closure.</p> <p><i>Injury to penis</i>—Limited superficial laceration or burn injury not requiring additional dressings.</p>	<p><i>Excess skin removal</i>—Tightness of the skin discernible and additional sutures or skin mobilization needed for wound closure, but no other intervention needed.</p> <p><i>Injury to penis</i>—Abrasion or small laceration of glans or shaft or small burn injury requiring prolonged intra-operative attention to treat or pressure dressing, but surgical repair not required.</p>	<p><i>Excess skin removal</i>—Provider unable to close wound; referral to another facility required.</p> <p><i>Injury to penis</i>—Severe laceration or severing of the glans or shaft, damage to the urethra that requires additional surgery to repair the injury, significant diathermy burn injuries.</p>
Device	<p><i>Excess skin removal</i>—NA</p> <p><i>Injury to penis</i>—Limited superficial injury not requiring additional intervention.</p>	<p><i>Excess skin removal</i>—NA</p> <p><i>Injury to penis</i>—Abrasion or small laceration of the glans or shaft requiring pressure dressing, but surgical repair is not required.</p>	<p><i>Excess skin removal</i>—NA</p> <p><i>Injury to penis</i>—Injury that requires surgical intervention to stop bleeding or repair.</p>

Adverse Event Classifications and Definitions: Post-Operative Period after Discharge from VMMC Clinic or During or After Device Removal

ADVERSE EVENT	MILD	MODERATE	SEVERE
BL: BLEEDING			
Surgery	Blood-stained dressings or underwear; no active bleeding. Small amount of bleeding from minor clot disruption when changing dressings that is controllable with new dressings or 5–10 minutes of manual pressure measured on a clock.	Bleeding that is not controlled by new dressings or 5–10 minutes of manual pressure measured on a clock, and requires a special return to the clinic for a pressure dressing or additional skin sutures without surgical re-exploration of the wound.	Bleeding that requires surgical re-exploration, hospitalization, or transfer to another facility; or any case where blood transfusion or intravenous fluid is necessary.
Device	Small amount of bleeding from wound with no active bleeding and is controllable with new dressings or 5–10 minutes of manual pressure.	Bleeding that is not controlled by new dressings or 5–10 minutes of manual pressure or requires a special return to the clinic for a pressure dressing or additional skin sutures without surgical re-exploration of the wound.	Bleeding that requires surgical re-exploration, hospitalization, or transfer to another facility; or any case where blood transfusion or intravenous fluid is necessary.
DD: DEVICE DISPLACEMENT			
Device	N/A	Displacement of the device, including intentional movement of device by the client and/or self-removal that does not require surgical intervention to correct, either because the device can be removed, repositioned, or replaced with a new device.	Displacement of the device, including intentional movement of device by the client and/or self-removal, that requires surgical intervention to correct, or requires hospitalization or transfer to another facility to clinically manage.
IN: INFECTION			
Surgery and Device	Erythema or traces of serous discharge or infective process noted at wound margin. No intervention other than improved wound hygiene.	Discharge from the wound, painful swelling with erythema, or elevated temperature that requires use of oral antibiotics.	Cellulitis or abscess of the wound, or infection severe enough to require surgical intervention, hospitalization, or intravenous or intramuscular antibiotics.
PA: PAIN			
Surgery	Client complains of pain, not requiring more than standard post-operative analgesics and considered within normal thresholds associated with surgery.	Pain serious enough to result in disability (as evidenced by loss of work or cancellation of normal activities) that lasts for at least 1 day after surgery.	Pain serious enough to result in disability (as evidenced by loss of work or cancellation of normal activities) lasting 2 or more days after surgery.

ADVERSE EVENT	MILD	MODERATE	SEVERE
Device	Client complains of pain, not requiring more than standard post-operative analgesics and considered within normal thresholds associated with surgery.	Pain serious enough to result in disability (as evidenced by inability to work or perform activities of daily living) lasting for at least 1 day after device placement or removal. For programs that utilize a visual analogue scale (VAS) for rating severity, a VAS score of 5–7 (on a 1–10 scale).	Pain serious enough to result in disability (as evidenced by inability to work or perform activities of daily living) lasting 2 or more days after device placement or removal. For programs that utilize a visual analogue scale (VAS) for rating severity of pain, a VAS score of 8–10 (on a 1–10 scale).

SD: SCARRING/DISFIGUREMENT/POOR COSMETIC RESULT; EXCESS SKIN REMOVAL; INJURY TO PENIS

Scarring/disfigurement/poor cosmetic result; excess skin removal	<p><i>Scarring</i>—Complaints by client in the absence of discernible abnormal scarring or disfigurement.</p> <p><i>Torsion of penis</i>—Torsion present but does not cause pain or discomfort.</p> <p><i>Insufficient skin removal</i>—Prepuce extends over the coronal margin but less than one third of the glans is covered in flaccid state.</p>	<p><i>Scarring</i>—Discernible but re-operation not required. Usually noticed first by the client and reported to the provider.</p> <p><i>Torsion of penis</i>—Torsion present that causes mild pain or discomfort with erection but does not require surgery to correct.</p> <p><i>Insufficient skin removal</i>—Prepuce partially covers glans when flaccid but surgical correction is not necessary.</p>	<p><i>Scarring</i>—Discernible and requires re-operation or referral/transfer to another facility.</p> <p><i>Torsion of penis</i>—Torsion present. Erections are painful and client cannot tolerate the appearance, discomfort, or pain. Surgery needed for correction.</p> <p><i>Insufficient skin removal</i>—Prepuce covers most of the glans when flaccid and surgical correction is necessary.</p>
Surgery and Device			
Injury to penis—Surgery	<i>Injury to penis</i> —Bruising or abrasion, or limited superficial laceration, or burn injury not requiring additional dressings.	<i>Injury to penis</i> —Significant laceration or burn injury requiring either prolonged follow-up care and attention, or repeated or additional dressings, but not requiring surgical correction or hospitalization.	<i>Injury to penis</i> —Significant injury including laceration or severed portion of glans; damage to the urethra or shaft laceration with ongoing bleeding that requires hospitalization, development of a fistula, transfer or transfusion; or significant burn injury leading to significant tissue necrosis/loss. Laceration or severed tissue should be evident at the time of surgery but severe diathermy burns or even coagulation of blood in the whole penis may not be evident until a day or two later. In the case of diathermy urethral injury, leakage of urine through the circumcision wound may occur some days later.-

ADVERSE EVENT	MILD	MODERATE	SEVERE
Injury to penis–Device	<i>Injury to penis</i> –Limited superficial injury not requiring additional intervention.	<i>Injury to penis</i> –Bruise or abrasion of the glans or shaft requiring pressure dressing, but surgical repair is not required.	<i>Injury to penis</i> –Injury that requires surgical intervention to stop bleeding or to repair. Severing of the glans or shaft, injury to urethra or development of a fistula is also considered a severe AE.
Excess skin removal–Surgery	<i>Excess skin removal</i> –Slight tightening of the skin observed; no surgical correction needed.	<i>Excess skin removal</i> –Pulling of scrotal skin onto the penile shaft, wound disruption or disruption of sutures due to tension on stitches.	<i>Excess skin removal</i> –Wound appearance is such that the wound has gaping edges or large or deep defects such that without revision, there would be significant scar formation.
Excess skin removal–Device	<i>Excess skin removal</i> –Slight tightening of the skin observed; no surgical correction needed.	<i>Excess skin removal</i> –Pulling of scrotal skin onto the penile shaft and wound disruption.	<i>Excess skin removal</i> –Wound appearance is such that the wound has gaping edges or large or deep defects such that without revision, there would be significant scar formation.
SX: SEXUAL EFFECTS/UNDESIRABLE SENSORY CHANGES			
Surgery and Device	Occasional inability to have erection or dissatisfaction with sexual performance; no psycho-behavioral consequences.	Post-operative changes that consistently impair or preclude sexual function for three to six months after surgery; these issues were not present prior to surgery.	Post-operative changes that consistently impair or preclude sexual function for greater than six months after surgery; these issues were not present prior to surgery.
WD: WOUND DISRUPTION			
Surgery	Wound disruption but not extensive enough to require suturing for wound closure (<1.0 cm).	Wound disruption extensive enough to require suturing or other clinical intervention but not surgery, (> 1.0 cm).	Surgical re-exploration or repair is required, or referral/transfer to another facility or hospitalization is required.
Device	Wound disruption but not extensive enough to require suturing for wound closure.	Muco-cutaneous gap > 1.0 cm in width, but no exposure of deeper tissue.	Wound disruption exposing tissue deeper than subcutaneous tissue or requiring surgical intervention such as suturing or debridement.

ADVERSE EVENT	MILD	MODERATE	SEVERE
OA: OTHER ADVERSE EVENTS/EXCESS SWELLING OF PENIS OR SCROTUM, INCLUDING HEMATOMA; DIFFICULTY URINATING, OR OTHER			
Surgery and Device	<p><i>Excess swelling</i>—Mild swelling without signs of on-going bleeding.</p> <p><i>Other</i>—N/A.</p>	<p><i>Excess swelling</i>—Symptoms/signs that require clinical intervention, but not surgical exploration.</p> <p><i>Other</i>—Other adverse events related to surgery that result in disability (as evidenced by loss of work or cancellation of normal activities) lasting for at least 4 days after surgery but not more than 7 days.</p>	<p><i>Excess swelling</i>—Surgical exploration required to control bleeding or remove hematoma or symptoms/signs so extraordinary as to cause disability (as evidenced by loss of work or cancellation of normal activities) lasting for at least 8 days after surgery or device placement or removal as pertinent.</p> <p><i>Other</i>—Other AE(s) related to the surgery that result in disability (as evidenced by loss of work or cancellation of normal activities) lasting for at least 8 days after surgery or device placement or removal, or result in hospitalization or referral/transfer to another facility.</p>
Difficulty Urinating –Surgery	N/A	Obstruction requiring a special return to the clinic but not surgical intervention or placement of a catheter (transient difficulty urinating that resolves on its own would not be considered an AE).	Complete obstruction and/or requires placement of a catheter, referral for treatment, or surgery to correct.
Difficulty Urinating –Device	N/A	Symptoms that resolve with removal/repositioning of the device or dressing (transient difficulty urinating that resolves on its own would not be considered an AE).	Complete obstruction and/or requires placement of a catheter, referral for treatment or surgery to correct.

Source: *Adverse Event Action Guide for Voluntary Medical Male Circumcision by Surgery or Device, 1st Edition, 2016.*

FOR ADDITIONAL INFORMATION

PREVENTING, MANAGING, AND DOCUMENTING AES

Surgical and medical procedures inherently involve risk. Severe AEs—including death—have occurred during and following VMMC. As PEPFAR programs reach greater numbers of VMMC clients, moderate and severe AEs will likely continue to occur as part of routine VMMC delivery (the average frequency rate is $\leq 2\%$). This does not (necessarily) indicate poor performance. Nevertheless, every program should ensure that all staff and sites are prepared with the appropriate knowledge, skills, and commodities to prevent AEs, manage those that do occur, and routinely document each occurrence.

Preventing AEs: The best way to prevent the occurrence of AEs is to ensure proper screening of clients seeking VMMC services to rule out contra-indications for surgery—anemia, high blood pressure, diabetes mellitus, sexually transmitted infections (STIs), hemophilia, and other conditions that make surgery risky. It is also important to identify contraindications for surgery, especially urogenital conditions such as undescended testis, hypospadias, epispadias, phimosis, and paraphimosis. [See [WHO Manual for Male Circumcision Under Local Anaesthesia, 1st edition](#)].

A special note about screening for bleeding disorders to prevent cases of intra-operative and post-operative excess bleeding: Bleeding disorders are a good example of an AE that may be avoided by obtaining a thorough medical history from each client. The [AE Action Guide for VMMC by Surgery or Device, 1st Edition, 2016](#), advises:

“In clients with bleeding abnormalities, bleeding during or immediately after surgery is difficult to control. The most common of these abnormalities are von Willebrand disease and hemophilia. Before MC, it is important for providers to question each client or, in the case of a minor, their parent or guardian, about whether there is a history of bleeding problems in the client or the family. If there is a history of a bleeding abnormality in the client or in others in the family, MC should not be undertaken under routine conditions. If there is uncertainty about whether a bleeding abnormality is present, there should be consultation with a specialist before providing MC. It is important to remember that in some people with less severe forms of these bleeding abnormalities, the problem becomes apparent only after there is a medical intervention such as a medical or dental procedure. MC may be the first such procedure that some clients undergo, especially younger clients, so it may be the instance where a previously undiagnosed bleeding abnormality becomes apparent. **As some bleeding disorders are hereditary, other family members of a client with a suspected or confirmed bleeding disorder could also be affected. Hemophilia is an inherited disorder that is passed from mothers to sons. In clients with suspected or confirmed hemophilia, brothers and cousins related through maternal aunts could also be affected and should not have MC performed until there is assurance that a bleeding disorder is not present**” (page 19).

Managing AEs: When AEs occur, they can only be managed with a well-prepared, well-equipped team. VMMC staff should be trained in identifying and clinically addressing AEs when they occur. Also, VMMC service locations should have equipment and supplies on site to manage AEs, staff trained to use the equipment and procedures for managing any (very unlikely) life-threatening complications that may occur. [See [Adverse Event Action Guide for Voluntary Medical Male Circumcision by Surgery or Device, 1st edition, 2016](#)]. This includes dealing with emergencies within the facility

or efficiently transferring the client to the nearest referral facility to ensure continuity of care. Sites should have a referral plan for emergency clients that is established before VMMC services are launched and includes the name and contact information of key specialty providers at the referral facility.

Educating Clients on VMMC and its Risks: Appropriate client education can also help prevent AEs. 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, avoiding application of substances possibly contaminated with tetanus). Clients also need to understand the risks of VMMC surgery, though AEs are rare. This should include information about the risks of tetanus, as well as ways to reduce the risk of tetanus.

Site staff must remind the client of the importance of adhering to postoperative follow-up recommendations set forth by the Ministry of Health, which typically recommend that clients return to a clinical site at two and seven days postoperative, regardless of healing status or complications. Clinicians should clearly indicate that sex within six weeks of surgery increases the risk for wound disruption and STI transmission, and is not recommended; and that resuming sex without a condom is particularly dangerous in this period. Clients must be informed of symptoms of complications and how to manage them correctly.

It is imperative that all clients know where to find emergency care. All clients should be provided with phone numbers they can call for emergency services, if complications arise.

Guidance on emergency equipment/supplies is provided by PEPFAR through the annual PEPFAR Technical Considerations and readiness assessments are specifically recommended as part of quality assurance activities. [See [Chapter 10](#)]. U.S. 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, that supplies haven't reached their date of expiration, and that staff members are trained to use the emergency equipment/supplies (at least once every 12 months) and are always available when VMMC services are being provided.

Monitoring and Reporting AEs: Once AEs have been correctly diagnosed and managed, their occurrence and treatment must be documented and tracked appropriately—either on a client record or on a separate AE form. As part of diagnosing AEs, providers should categorize all AEs as mild, moderate, or severe. Additional suggestions for classifying the type, timing, and severity of AEs, as well as instructions for clinical management of AEs, can be found in the updated adverse event action guide. [See [Adverse Event Action Guide for Voluntary Medical Male Circumcision by Surgery or Device, 1st Edition, 2016](#)].

VMMC programs are advised to track AEs using an AE register, where AE resolution and other parameters can easily be monitored. Program should also conduct regular AE audit meetings involving all VMMC staff and senior clinicians, and discuss management and resolution, or ongoing treatment of those AEs not yet resolved. Programs should maintain the minutes of these meetings to track decisions. Over time, this information can be used to identify and address problems in service provision.

Referring or Transferring Clients: Most AEs can be managed at the VMMC site, but facilities must establish an appropriate referral system to guarantee efficient referral to a higher-level or better-equipped facility/provider, as the need arises. The name and contact information of key specialty providers at the referral facility should be pre-defined, and the referral relationship between the facilities should be established before VMMC services are launched.

VMMC and Tetanus Risk: During 2012 and 2015, some priority VMMC countries experienced the occurrence of



tetanus cases and fatalities in their programs for the first time since the VMMC scale-up VMMC began. Due to the severity of tetanus disease, and the absence of protective immunization policies for males in many priority VMMC countries, WHO and PEPFAR developed resources to help national programs and service sites to mitigate tetanus risk among VMMC clients. The WHO document [See [Tetanus and Voluntary Medical Male Circumcision: Risk According to Circumcision Method and Risk Mitigation, Report of the WHO Technical Advisory Group, 12 August 2016](#)], summarizes the risk of tetanus in the VMMC context and proposes risk mitigation strategies, including vaccination.

Once countries articulate their national strategy for tetanus risk mitigation, which may include immunization as part of the VMMC service package, site level staff should reference PEPFAR's practice guidance. [See [Considerations for PEPFAR-Supported VMMC Programs Incorporating Tetanus Vaccination and Other Risk Mitigation Activities and Chapter 10](#)].

This resource covers a wider variety of topics including communications, clinical considerations, and supply chain requirements, to name a few.

Conducting Site Assessments: Readiness assessments are specifically recommended as part of quality assurance activities for VMMC facilities supported by the U.S. Government agencies and implementing partners must assess all VMMC service sites to verify that (1) the required emergency equipment and supplies are on site and readily available; (2) supplies are current (unexpired); (3) staff members receive at least annual training on using the emergency equipment/supplies; and (4) trained staff are always available when VMMC services are being provided.

Calculating AE Rate: It is important to monitor and calculate the rate of moderate and severe AEs accurately both 1) in each service delivery site and 2) in the program as a whole, to ensure that the rates do not exceed the expected rate of moderate and severe AEs. AE rates can be calculated by the number of clients with a moderate or severe AE(s)/total number of clients followed up. Intraoperative and post-operative surgical AE rates are calculated differently, as are AE rates for devices, primarily due to the use of different denominators. For intra-operative surgical AEs, the rate is calculated as the number of clients with a moderate or severe AE(s)/total number of all clients undergoing surgical circumcision. For post-operative surgical AEs, the rate is calculated as the number of clients with a moderate or severe AE(s)/total number clients returning to the site for follow-up in person. For device-based AE(s), the rate is calculated as the number of clients with a moderate or severe AE(s)/total number of all clients having a device placed. If a client does not return to a facility for follow-up care, then that client should not be counted in the AE rate denominator. Studies have shown that clients who fail to return for at least one of the visits are not necessarily free from AEs, and may even have higher AE rates than those who come for follow-up (Reed et al. 2015). Staff are therefore advised to make an effort to make a follow-up call, or make a physical follow-up to the home for all clients who fail to return for the recommended follow-up visit(s). It is also advised to document follow-up attempts, even when they are failed attempts. Note that only those clients followed-up in person count in the denominator for surgical post-operative AE rates; those followed up only by phone are not included in the denominator.

CASE STUDIES

Three case studies, all drawn from interventions/programs in Uganda, illustrate approaches that have been used to address AE monitoring, reporting and management in specific settings (see below).

[Case Study 7.1. Managing VMMC-Related Adverse Events in the Mobile Van Clinic in Uganda](#)

[Case Study 7.2. Improving Quality while Scaling Up Safe Male Circumcision Services in Uganda](#)

[Case Study 7.3. Enhanced Counseling and Documentation to Reduce Adverse Events among Circumcised Clients in Uganda](#)

TOOLS, INSTRUMENTS & GUIDANCE DOCUMENTS

The following documents, which are available online and in the accompanying external media (included with the hard copy version of this Guide), provide the background information or procedural guidance used for development of this chapter.

1. [Tetanus and Voluntary Medical Male Circumcision: Risk According to Circumcision Method and Risk Mitigation, Report of the WHO Technical Advisory Group, 12 August 2016](#)
2. [WHO Manual for Male Circumcision Under Local Anaesthesia, 1st edition](#)
3. [Adverse Event Action Guide for Voluntary Medical Male Circumcision by Surgery or Device, 1st Edition, 2016](#)
4. [PEPFAR Monitoring, Evaluation, and Reporting Indicator Reference Guide](#)
5. **PEPFAR Reporting Protocol for VMMC Client Death and Notifiable Adverse Events, Form 1:** Can be obtained by contacting in-country USAID Mission staff.

REFERENCE

Reed, J., J. Grund, Y. Liu, et al. 2015. "Evaluation of loss-to-follow-up and adverse events in a voluntary medical male circumcision program in Nyanza Province, Kenya," *Journal of Acquired Immune Deficiency Syndromes* (January 2015), 69:e13-e23.

ABBREVIATIONS

AE	adverse event
HIV	human immunodeficiency virus
M&E	monitoring and evaluation
MOH	Ministry of Health
PEPFAR	United States President’s Emergency Plan for AIDS Relief
SIMS	Site Improvement through Monitoring Systems
USAID	United States Agency for International Development
VMMC	voluntary medical male circumcision
WHO	World Health Organization



CASE STUDY 7.1.

Managing VMMC-Related Adverse Events in the Mobile Van Clinic in Uganda

The mobile van clinic offers safe male circumcision (SMC) services in four districts supported by Makerere University Walter Reed Project (MUWRP) with funding from the U.S. President's Emergency Plan for AIDS Relief through the U.S. Department of Defence. In March 2013, the USAID Applying Science to Strengthen and Improve Systems Project (ASSIST) conducted a baseline quality assessment that identified problems with adverse event (AE) management.

PROBLEM

In April 2013, the clinic had an AE rate of ~5.5 percent, especially among 13–15 year-olds. The team, with help from the USAID ASSIST Project, used the mobile clinic's performance data and records to identify the following root causes of this high AE rate:

1. Lack of a structured quality improvement team at the service site
2. Absence of quality reviews or meetings to review client charts
3. Data collected but not used to inform decision-making
4. No attendance at information system by parents and/or guardians of minor adolescents; they signed the parental/guardian consent and left the site
5. Inadequate verification that clients understood instructions or information about aftercare; most adverse events were related to a failure to follow instructions, such as keeping the wound dry.

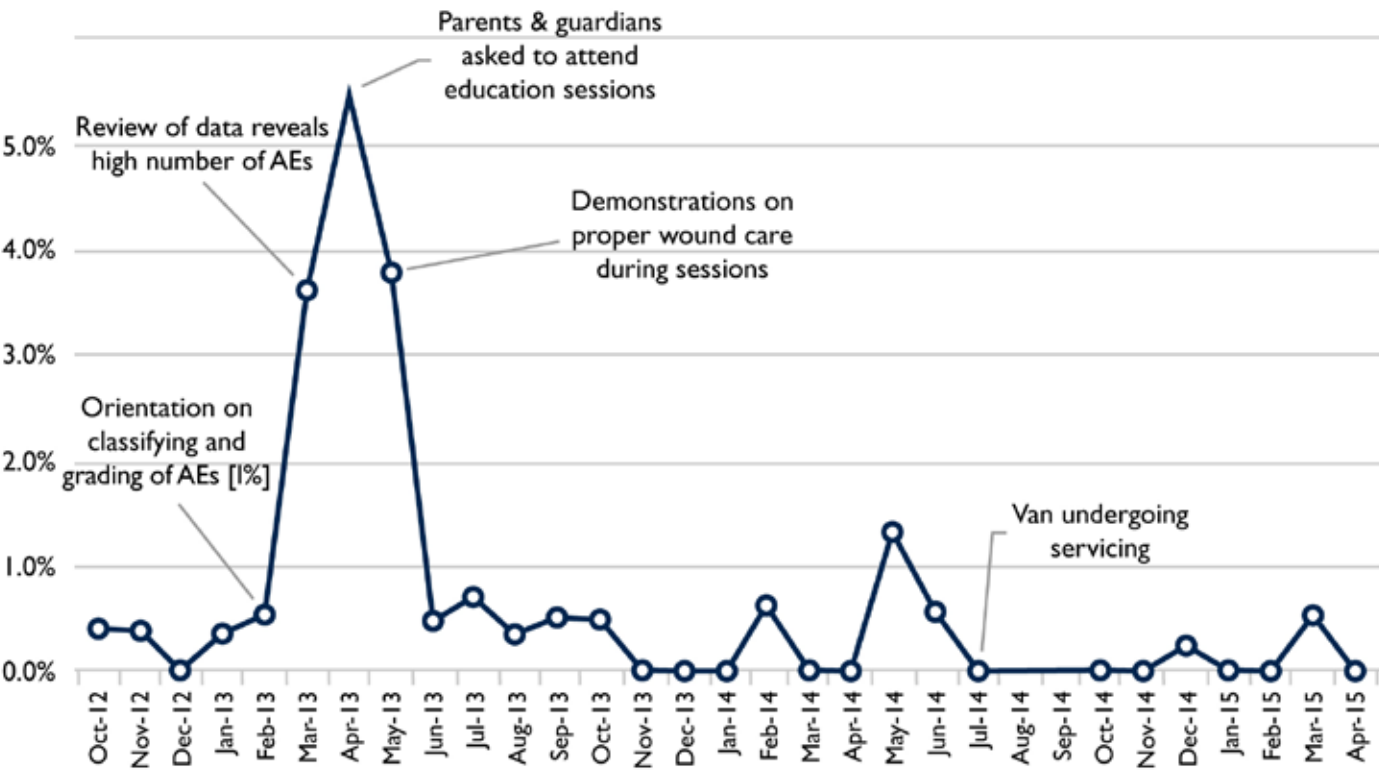
IMPROVEMENT APPROACH

USAID ASSIST Project, MUWRP, and district health representatives worked with the mobile clinic to address identified quality gaps by:

- Forming a quality improvement team
- Training the team in proven quality improvement approaches
- Mentoring the team to start analyzing and making decisions based on their performance by using collected data, including data on infection prevention and control practices, client audit, and client follow-ups
- Conducting monthly coaching and mentorship visits
- Advising parents or guardians of minors to attend and support their children throughout the procedure, and to give them more support at home using information learned during the sessions.

RESULTS

AEs dropped to an average rate of <0.5 percent (see Figure 7.1.1.).



CASE STUDY 7.2.

Improving Quality while Scaling Up Safe Male Circumcision Services in Uganda

The AIDS Support Organization (TASO) Tororo, a nongovernmental organization based in Uganda, implements safe male circumcision (SMC) services in Uganda with funding from the U.S. Centers for Disease Control and Prevention.

PROBLEM

During the initial activities for scaling up SMC services, considerable emphasis was placed on meeting yearly targets, but some quality issues persisted. The adverse event (AE) rate at TASO Tororo was high, at 4.8 percent, and the post-operative follow-up rate after circumcision was undesirable, at 56 percent. In April 2014, the SMC team identified this as a problem and started a quality improvement project with the aim of reducing AEs from 4.8 percent to 2 percent, and increasing the follow-up rates at 48 hours, 7 days, and after 7 days from 56 percent to 100 percent over one year.

IMPROVEMENT APPROACH

The team:

- Identified the root causes of high AE rate among circumcised clients
- Conducted radio talk shows addressing potential harmful VMMC wound care practices, including use of traditional medicine
- Made reminder phone calls to clients and village health teams to help with adherence to follow-up
- Scheduled centralized client post-circumcision reviews within the community such as schools and churches
- Documented each client visit on the client form and in the VMMC register
- Tracked, graded, and managed each severe AE until it was resolved.

RESULTS

Between April 2014 and March 2015, 100 percent of the 7,778 clients who received circumcision returned for follow up within 7 days. In addition, the proportion of moderate and severe AEs decreased from 4.8 percent in 2014 to 0.9 percent in March 2015.



CASE STUDY 7.3.

Enhanced Counseling and Documentation to Reduce Adverse Events among Circumcised Clients in Uganda

PROBLEM

The USAID Applying Science to Strengthen and Improve Systems (ASSIST) Project and the Ministry of Health of Uganda conducted an assessment at 49 sites that reported only 0.8 percent of circumcised clients had developed complications. After further investigation, it appeared the low adverse event (AE) rate was related to poor identification of AEs and/or underreporting. They also noted that some clients received group counseling, not individual counseling, and were thus inadequately informed about VMMC.

IMPROVEMENT APPROACH

The USAID ASSIST Project led efforts to improve the quality of VMMC services at all the sites, including one rural hospital. The sites formed a VMMC continuous quality improvement (CQI) team and site action plan. The plan included:

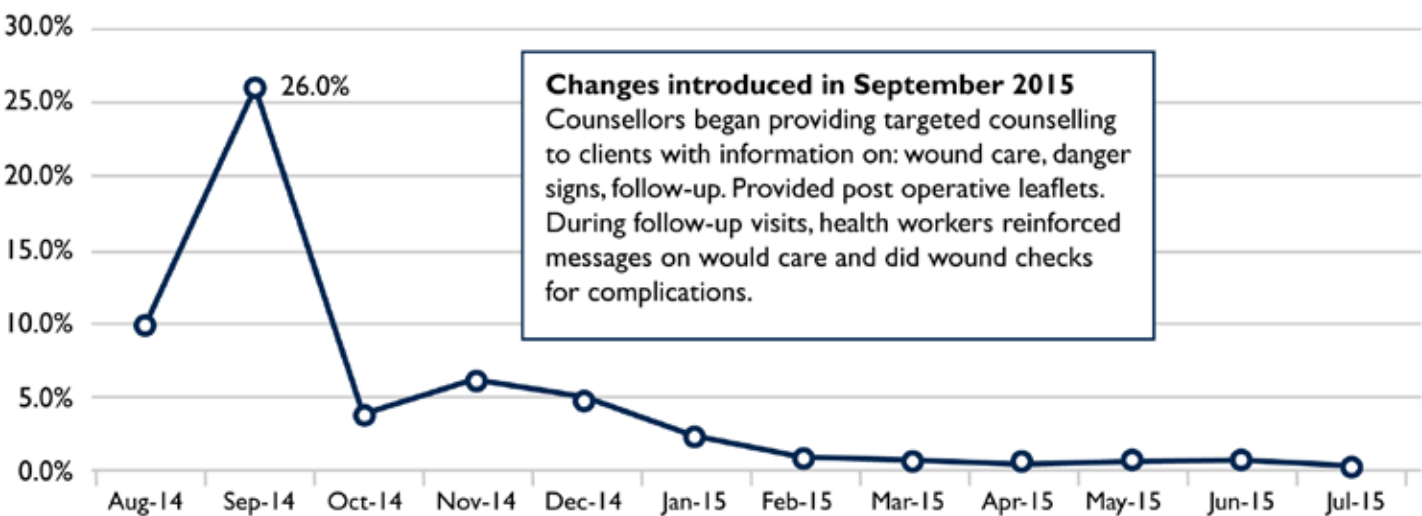
- Reviewing baseline findings to define and find root causes of gaps
- Training, coaching and mentoring staff at the site on preventing, identifying, managing, reporting, and tracking adverse events
- Introducing missing tools, revising existing tools, and working with the team on using tools, including AE registers, client audit meetings, and data, to inform decisions.

The VMMC CQI team further reorganized counseling sessions. They introduced counselors on a rotational basis to provide information on: 1) wound care before and after surgery, including avoiding application of homemade portions such as cow dung on the wound; 2) danger signs and facility contacts to call in case of any complications; 3) the need to return for post-operative follow-up; 4) wound care and checks during follow-up visits for signs of complications and management; and 5) post-operative instruction through leaflets on wound care to clients.

RESULTS

Between August and September 2014, the AE rate initially rose to 26 percent as clinicians adapted to the AE definitions and documentation practices. The VMMC CQI team worked to improve identification, grading and overall clinical management of AEs. Shortly thereafter, the AE rate fell substantially, and by July 2015, the rate of AEs dropped to 0.4 percent, as shown in the time series chart below.

Figure 7.3.1. Percentage of Circumcised Clients Presenting with Moderate to Severe Adverse Events in Hospital K, Central Region, Uganda



CHAPTER 8.

Monitoring & Evaluation and Research

CHAPTER GOALS

For MONITORING & EVALUATION, to ensure site staff are able to:

- Collect, analyze, and utilize routine data from VMMC service provision and performance standards to appropriately monitor the quality and safety of VMMC services and respond as needed.

For RESEARCH & FORMAL EVALUATIONS, to ensure site staff are able to:

- Participate in periodic formal evaluations and research studies that address issues not captured in routine monitoring and evaluation (M&E) by providing adequate background information.

WHAT USERS NEED TO KNOW

MONITORING & EVALUATION

Monitoring and evaluation are means of tracking progress and reviewing outcomes of a specific program with the goal of program improvement. Monitoring and reporting activities that collect, aggregate (combine), and share service provision data are an essential component of a VMMC program. VMMC programs should have the capacity to capture and track key required indicators regarding service delivery as well as safety and quality. Monitoring of VMMC programs is described in depth at [PEPFAR Monitoring, Evaluation, and Reporting Indicator Reference Guide](#) and [Table 8.1](#).

RESEARCH & FORMAL EVALUATIONS

Research in VMMC programs is conducted to advance the state of knowledge about VMMC practices so that global and local policies and program implementation can be improved. Research and formal evaluations are an important corollary approach to routine monitoring of VMMC services; they are used to answer specific questions related to quality, service delivery approaches, demand for, or utilization of services. Facility administrators, site managers, and facility clinical staff may either design and lead or be asked to participate in these studies from time to time. Anyone participating in IRB-reviewed research should, in addition to meeting organizational requirements, have training in research ethics. An internationally recognized online course is offered by CITI (Collaborative Institutional Training Initiative) which provides an overview of research ethics [See [CITI Training](#)].

FREQUENTLY REFERENCED MONITORING & EVALUATION INFORMATION

PEPFAR AND PROGRAM MONITORING INDICATORS

An indicator quantifies performance and is a measurable number, proportion, percentage, ratio, or rate that reports program achievements. Similar to other PEPFAR programs, the VMMC program has specific indicators on which every funded partner who supports or provides VMMC services must report.

Table 8.1 presents the VMMC indicator on which all PEPFAR-funded implementing partners must report. HIV testing services that occur within PEPFAR-funded VMMC, should also be reported, separately, using the HTS_TST indicator as explained in PEPFAR's MER 2.0 Guide.

FOR ADDITIONAL INFORMATION ON MONITORING AND EVALUATION

VMMC programs must have the capacity to capture and track key indicators regarding service delivery as well as safety and quality. Reporting must take place both to PEPFAR, using such formats as the Annual (APR) and Semi-Annual Program Results (SAPR) Reports, Quarterly Performance Reviews, and PEPFAR Oversight Accountability Report Team (POART), and to ministries of health or private sector associations as warranted in different country programs. Additionally, PEPFAR team members will examine performance indicators, expenditure of programs, and quality of services on a monthly basis.

Monitoring systems can be diverse between countries based on available infrastructure for health information systems (HIS). Appropriate norms for reporting should be based on the country's reporting requirements, PEPFAR requirements, and the available infrastructure and resources. Client level reporting provides the most detail but requires more human resources and data management infrastructure, and it must conform to norms of client confidentiality in the country. Aggregate data, which is the norm in most HIS, are generally sufficient to track necessary data for VMMC reporting, including the VMMC and HIV testing PEPFAR MER (monitoring, evaluation, and reporting) indicators (see **Table 8.1**).

Client records, client registers, and monthly summary forms are necessary site-level building blocks of any service delivery tracking system, unless the system is a full electronic medical record system (eMRS). Sample tools, which form the foundation of routine service delivery, are provided in the following: **VMMC Client Record Form**, **VMMC Monthly Reporting Form**, and **VMMC Client Register**, as templates that may be adapted to individual country needs. In addition to the routine service delivery monitoring, supervision visits, such as external quality assessment [EQA], quality improvement/assurance initiatives such as continuous quality improvement [CQI], and PEPFAR's Site Improvement and Monitoring Systems [SIMS] [See **Chapter 10**], as well as client exit interviews, all provide opportunities to review routine data for quality or gather information to guide quality improvement.

As with any other health service, VMMC service monitoring requires:

- National indicators
- Standardized national data collection tools (including client records, client registers, and monthly summary forms)
- Systems and protocols for data flow
- Data management system (can be electronic or paper-based, or a combination).

Table 8.1. PEPFAR VMMC Indicators (from PEPFAR 2016 Monitoring, Evaluation, and Reporting [MER] Indicator Reference Guide 2.0)

Note: PEPFAR indicators change periodically so these indicators should be reviewed online

PEPFAR INDICATOR: VMMC_CIRC PROGRAM AREA: VMMC		
DESCRIPTION	Number of males circumcised as part of the voluntary medical male circumcision (VMMC) for HIV prevention program within the reporting period	
NUMERATOR	Number of males circumcised as part of the voluntary medical male circumcision (VMMC) for HIV prevention program within the reporting period	Additional information about numerator definition N/A
DENOMINATOR	N/A	N/A
MER 1.0 TO 2.0 CHANGE	Age disaggregate improved to align with VMMC technical considerations. Follow-up disaggregation to include device-based VMMC.	
HOW TO USE	Tracks the number of VMMCs conducted during the reporting period, a key component of determining coverage of circumcision in the population over time, as well as supply of and/or demand for VMMC services. Disaggregations (by age, HIV status, and circumcision technique) are required and are used to evaluate whether prioritized services have been successful at reaching the intended population and whether targets have been achieved. Modeling inputs should be adjusted as information on VMMCs by disaggregation accumulates. Attendance at follow-up visits should also be tracked, since postoperative clinical assessments are part of good clinical care, and low follow-up rates may indicate a problem in program quality.	
DISAGGREGATION DEFINITIONS	Age: <1 years, 1–9 years, 10–14 years, 15–19 years, 20–24 years, 25–29 years, 30–49, 50+ years HIV status: number of HIV-positive clients (tested HIV positive at VMMC site), number of HIV-negative clients (tested HIV negative at VMMC program), number of clients with undocumented/indeterminate HIV status or not tested for HIV at site	
	Circumcision technique: surgical VMMC, device-based VMMC	
	Follow-up status of surgical VMMC clients: number of surgical VMMC clients who returned at least once for follow-up care within 14 days of surgery; number of surgical VMMC clients who did not return for follow-up care within 14 days of surgery	
HOW TO COLLECT	The numerator can be generated by counting the number of males circumcised as part of the VMMC for HIV prevention program. This information can generally be found in the VMMC Register or in client medical records maintained by each program/site/service provider.	
HOW OFTEN TO REPORT	Monthly or quarterly	
HOW TO REVIEW FOR DATA QUALITY	Numerator ≥ subtotal of each of the disaggregations.	
HOW TO CALCULATE ANNUAL TOTAL	Sum across all reporting periods.	

Table 8.2. Important Non PEPFAR-required VMMC Program Quality Indicators

PEPFAR Indicator	Recommended or Required Disaggregation Level(s)
Number of circumcised clients experiencing at least one moderate or severe adverse event (AE) during or following surgery within the reporting period. All notifiable adverse events (AE) must be reported on the same day they occur to the relevant funding agency (CDC, USAID, DOD) and to the PEPFAR Coordinator in country, using the appropriate form.	Severity of AE, time of onset, and type of AE collected at site level
Number of locations providing male circumcision surgery as part of the minimum package of VMMC for HIV prevention services within the reporting period	Site location
Number of health care workers who successfully completed an in-service training program	All program areas

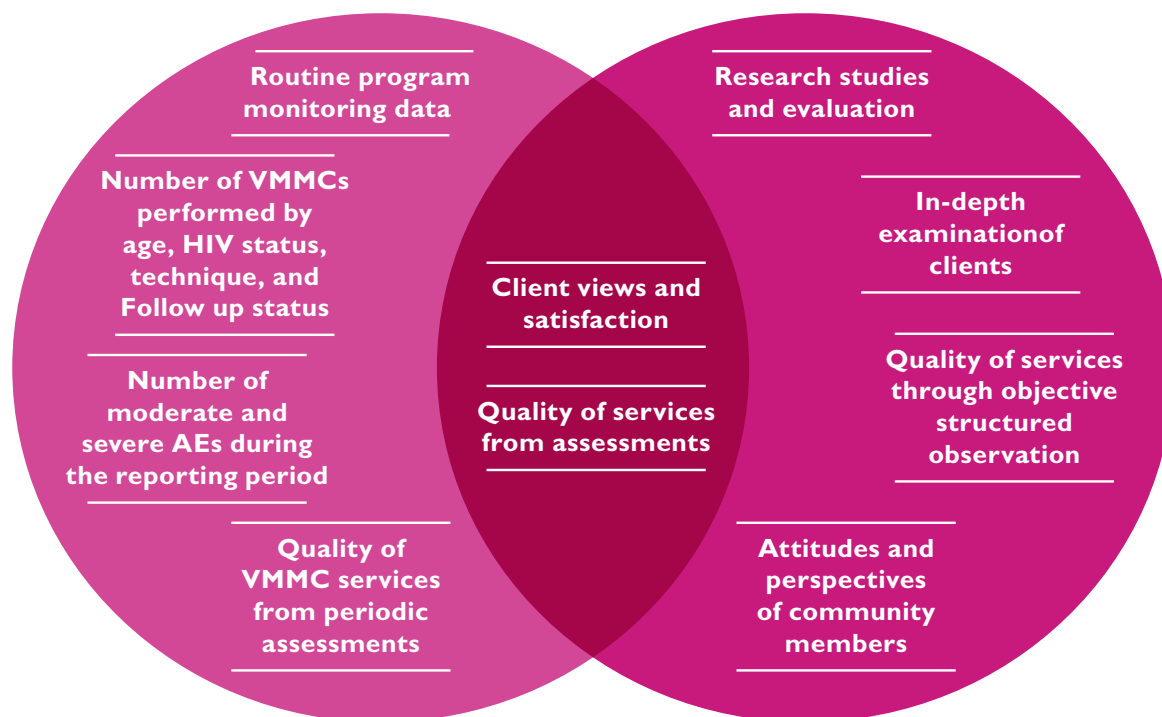
OTHER IMPORTANT AREAS FOR MONITORING VMMC SERVICES

As demand creation becomes more refined within VMMC programs, monitoring of community mobilization data has become increasingly important. Although none of the PEPFAR reported indicators described above are demand creation indicators, VMMC program implementers are urged to collect routine information that will inform and guide demand creation efforts. These data may include: the number of people reached with VMMC demand creation activities or messages, stratified by age; materials distributed; and number of people referred in to the VMMC program by peer mobilizers, among others.

WHAT USERS NEED TO KNOW ABOUT RESEARCH & FORMAL EVALUATIONS

Not all aspects of VMMC programs are captured in routine data. Figure 8.1 shows some program components that are well suited to routine program monitoring and some that may be better addressed through research studies. Studies that require independent additional data collection with more rigor, attention to detail, and often ethical oversight by institutional review boards are more costly to implement than routine program monitoring. However, they are sometimes necessary to answer in-depth or specialized questions about program quality or clinical practice, attitudes, and perceptions both in the community and among clients.

Figure 8.1. Sample Program Components for Routine Monitoring or Studies



Site management may either decide to design and conduct a study or formal evaluation from time to time, or the ministry of health may request that site management participate in a single or multi-country study related to VMMC.

TOOLS, INSTRUMENTS, AND GUIDANCE DOCUMENTS (7)

1. [PEPFAR Monitoring, Evaluation, and Reporting \(MER 2.0\) Indicator Reference Guide](#)
2. [CITI Training](#)
3. [VMMC Client Record Form](#)
4. [VMMC Monthly Reporting Form](#)
5. [VMMC Client Register](#)
6. [PEPFAR Guidance for Monitoring & Reporting VMMC Indicators](#)

ABBREVIATIONS

AE	adverse event
APR	Annual Program Results Report
CITI	Collaborative Institutional Training Initiative
CQI	Continuous Quality Improvement
eMRS	electronic medical record system
EQA	external quality assessment
HIS	health information systems
MER	monitoring, evaluation, and reporting indicators
PEPFAR	United States President’s Emergency Plan for AIDS Relief
POART	PEPFAR Oversight Accountability Report Team
SAE	severe adverse events
SAPR	Semi-Annual Program Results Report
SIMS	PEPFAR’s Site Improvement and Monitoring System
VMMC	voluntary medical male circumcision

CHAPTER 9.

Injection Safety & Health Care Waste Management

CHAPTER GOALS

To ensure site-level staff are able to:

- Use safe injection practices to prevent the spread of pathogens (especially bloodborne pathogens) to clients or providers
- Properly manage waste generated by VMMC services to protect health care workers, the community, and the environment.

WHAT USERS NEED TO KNOW

INJECTION SAFETY

Appropriate single use and disposal of both needles and syringes is an important topic because it touches upon not only waste management but also client and provider safety. Bacteria from skin and other surfaces and bloodborne pathogens may contaminate both needle (on contact and during aspiration) and syringe (during aspiration).

Therefore, providers must never access an anesthetic vial with either a needle or a syringe that has been used on a client, including for the purpose of drawing up more anesthetic for the same client. Providers may be tempted to change the needle but reuse the same syringe; however, this does not remove the risk of transmission, as blood may have entered the syringe. Instead, if a client needs additional anesthetic during a procedure, **a new needle and a new syringe** should be used to draw the anesthetic and reinject.

Key safe injection practices to prevent transmission of infections to clients or providers include:

- **Never** access any medication vial with a previously used syringe or needle (“double dipping”). If a client needs additional anesthetic during a procedure, use **a new needle and syringe** to draw the anesthetic and reinject. This carries a very small increased cost, and the risks of reuse are much more significant.
- **The best practice is to ensure anesthetic vials are not reused** between clients (they should be disposed of during cleanup after the VMMC procedure.) If a provider draws anesthetic for a client from a used vial, it is impossible to know whether the vial was contaminated by a prior provider who incorrectly “double-dipped” into it.
- If it is not possible to prevent anesthetic vial reuse, the only line of defense against blood-borne pathogen transmission is to ensure no provider ever double dips into a vial. Even if this is done, bacterial infection transmission is still possible, because every time a vial is accessed even with an unused needle, there is a risk of bacterial contamination.

- **Never** administer medications from the same syringe to more than one patient, even if the needle is changed.
- **Never use two hands to** recap used needles or use fingers to pick up a suture needle exposed to blood.
- **Always** dispose of used sharp instruments in sharps containers immediately after use.
- **Always** use aseptic technique when preparing and administering injections. This includes cleaning the vial septum properly before entering the vial to reduce the risk of bacterial contamination.
- **Always** ensure the sharps container is within arm's reach and not filled beyond two-thirds full before starting the procedure.

An open-access, 60-minute VMMC provider training module on injection safety is available online at [Injection Safety Training Module for VMMC Providers](#).

HEALTH CARE WASTE MANAGEMENT

To avoid serious *public health and legal consequences, as well as substantial environmental impact*, it is essential to develop safe and reliable methods for handling and treating health care waste. Proper waste management spans a number of stages from generation through disposal, thus service providers must have clear standard operating procedures on the segregation, packaging, handling, storage, transport, treatment, and disposal of waste [See [SCMS VMMC Health Care Waste Management Toolkit](#)]. Each site should have a health care waste management (HCWM) plan based on local norms and standards. Resources are available to assist site managers in developing their plan. Specifically prepared for VMMC service locations, the [SCMS VMMC Health Care Waste Management Toolkit](#) describes the steps of HCWM from collection to proper disposal employing user-friendly, highly illustrated standard operating procedures. The toolkit guides users in developing their own country-specific guideline document, such as the [Health Care Waste Management for VMMC Services: A Quick Guide](#), and provides examples of the standard operating procedures and waste management plans described above. Additional links on HCWM include the World Health Organization's (WHO) [Safe Management of Wastes from Health-Care Activities](#) and the United States Agency for International Development's (USAID) [USAID Sector Environmental Guidelines Healthcare Waste](#).

FREQUENTLY REFERENCED INFORMATION

INJECTION SAFETY

While the majority of local anesthetic injections are performed safely with little or no risk of infection, some can transmit infection to the client or provider if not done safely. The two types of infections that can be transmitted, both resulting from contamination of an injection needle, are as follows:

- Bacterial infections: A needle used to inject local anesthetic can become contaminated through contact with bacteria from any surface, including the client's skin, the provider's skin, or both, which bacteria can then be pulled into the syringe during aspiration.
- Bloodborne (usually viral) pathogen infections: A needle used to inject local anesthetic for a client infected with HIV, hepatitis B or C, or another bloodborne pathogen can become contaminated with that pathogen, which can then be pulled into the syringe during aspiration.

In both cases, if the contaminated needle or syringe is then used again to access a vial, the vial can become contaminated. If the same vial is later used for another client, the infection can be transmitted to that next client. Both bacterial and bloodborne pathogens have been transmitted in this way, causing multiple outbreaks of disease. Providers may be tempted to change the needle but reuse the same syringe. However, this does not remove the risk of transmission.

In the case of bloodborne pathogens, a provider can also become infected if s/he is stuck by the hollow injection needle.

The major administrative considerations for ensuring injection safety are:

- Ensuring an adequate supply of extra “loose” needles and syringes for anesthetic injection (that can be accessed without contaminating other sterile supplies, e.g., opening a new male circumcision (MC) kit).
- Ensuring that sharps containers are available at every procedure station and are not overfilled.
- Ensuring that sharps containers are accessible for use without contamination of the provider and out of the way for all staff traffic in operating or other rooms.

For more detailed information on injection safety, please reference the U.S. Centers for Disease Control and Prevention's [Frequently Asked Questions \(FAQs\) Regarding Safe Practices for Medical Injections](#) and WHO's (World Health Organization) [Safe Injection Global Network \(SIGN\)](#).

HEALTH CARE WASTE MANAGEMENT

Health care waste management (HCWM) spans a number of different stages from generation, to treatment, to disposal of waste (“cradle-to-grave”). To regulate the many steps spanning waste management, service providers must have clear standard operating procedures on the segregation, packaging, handling, storage, transport, treatment, and disposal of waste. The easiest way to establish proper HCWM is to draft a waste management plan based on local norms, standards, and/or guidelines. When developing/adapting a plan, you can refer to the following guidance materials. [See [Management of Solid Health Care Waste at Primary Health Care Centers: A Decision-Making Guide](#); [Environmental Health Management Toolkit for VMMC Services](#); [Health Care Waste Management for VMMC Services, Quick Guide for Tanzania](#); [Safe Management of Wastes from Health-Care Activities](#); and [USAID Sector Environmental Guidelines Healthcare Waste](#).]

This plan must address the HCWM process by carefully defining the necessary measures to be taken and allocating resources through cost-effective solutions. To ensure proper management, a successful HCWM plan should:

- Clearly define all points of generation of waste within the service site(s) (e.g., blood-drawing area, operating theater, HTC [HIV testing and counseling] areas, and recovery area).
- Propose HCWM product requirements/specifications.
- Include procedures and job aids for the identification, segregation, packaging, 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, and personal hygiene).
- Develop an incident reporting system.

- Propose environmentally sound treatment and disposal methods for the different streams of waste (infectious, sharps, chemical, and decontaminated non-sharp single-use metal instruments).
- Define relevant responsibilities of all staff, regional, and local governments.

The key to minimizing risk and minimizing waste is to effectively manage health care waste by identifying and segregating items based on the following VMMC-specific health care waste categories: general, pharmaceutical, infectious, sharps, and special (single-use metal instruments) waste. Identification and segregation are the responsibility of the staff that produce the waste and should occur as close as possible to the point of generation.

Formal protocols are needed to appropriately identify and segregate each category of waste. If the country's prevailing color-coding scheme is different from the one shown in Figure 9.1, the toolkit color-coding scheme and associated toolkit elements should be customized to comply accordingly. In the absence of colored bins, it's advisable to improvise with bins/bin-liners that can segregate the waste, with bin labels in the appropriate colors.

When designing a waste management system, it is essential to assess local infrastructure in order to determine which accepted options are the most practical for the country. Choosing among the options for the disposal of decontaminated, non-sharp, single-use metal instruments is an important step in the design of a sound HCWM system. Options for this waste stream, for example, could include burial of instruments in a secure sharps pits/concrete vault, transporting the instruments to a recycling/smelting facility, or specialized encapsulation.

Figure 9.1. Color coding relevant waste containers is a quick and easy way to identify segregated health care waste and visually indicate the contents of each container for waste handlers downstream. The color-coding scheme shown here is excerpted from the SCMS VMMC Health Care Waste Management Toolkit (2013).

Treatment of waste

	Pathological	Infectious	Sharps	Chemical (Including pharmaceutical)	Non-hazardous (General)
Treatment technology					
High temperature incineration with APC	✓	✓	✓	✓	✓
Low temperature incineration	✓	✓	✓		✓
Chemical disinfection		✓	✓		
Steam sterilization	✓	✓	✓		
Microwave radiation	✓	✓	✓		
Pit or bury			✓		✓
Encapsulation/ inertization				✓	
Composting (aerobic, vermiculture)					✓*
Anaerobic digestion (fermentation)					✓*
Engineered landfill					✓

*Only to be used for the treatment of non-hazardous/general food waste.

CASE STUDIES

Case Study 9.1. Ensuring Safe Health Care Waste Management and Environmental Hygiene through Innovative Tools

TOOLS, INSTRUMENTS & GUIDANCE DOCUMENTS

The following documents, which are available online and in the accompanying external media (included with the hard copy version of this Guide), provide the background information or procedural guidance used for development of this chapter.

1. [Environmental Health Management Toolkit for VMMC Services](#)
2. [Safe Management of Wastes from Health-Care Activities](#)
3. [Health Care Waste Management for VMMC Services, A Quick Guide](#)
4. [USAID Sector Environmental Guidelines Healthcare Waste](#)
5. [CDC Frequently Asked Questions \(FAQs\) Regarding Safe Practices for Medical Injections](#)
6. [WHO Safe Injection Global Network \(SIGN\)](#)
7. [Management of Solid Health Care Waste at Primary Health Care Centers: A Decision-Making Guide](#)
8. [Injection Safety Training Module for VMMC Providers](#)

ABBREVIATIONS

HCW	health care waste
HCWM	health care waste management
HTC	HIV testing and counseling
IEC	information, education, and communication
IPC	infection prevention and control
SCMS	Supply Chain Management System
USAID	United States Agency for International Development
VMMC	voluntary male medical circumcision
WHO	World Health Organization



CASE STUDY 9.1.


Ensuring Safe Health Care Waste Management and Environmental Hygiene through Innovative Tools

The importance of correctly handling health care waste (HCW) is globally underemphasized in preservice and in-service health care training curricula and quality management processes. Improving compliance with best practices of health care waste management (HCWM) has many benefits, including creating a safer clinical environment, increasing trust in the health care system, and providing financial savings. Some guidance about HCWM has been published, but it is not widely used. New tools are needed to increase uptake of HCWM best practices.

With the implementation of the VMMC initiative in Tanzania, proactive solutions for handling and disposing of HCW, as well as infection prevention and control (IPC) measures, were implemented to ensure the safety of patients, the public, health care providers, and the environment. To regulate the steps of managing HCW, SCMS through funding by USAID collaborated with Tanzania's Ministry of Health and Social Welfare and implementing partners to develop a quick guide with easy-to-follow illustrations that clearly defines national guidelines and procedures on environmental hygiene and HCW management. This innovative, more visual approach (see Figure 9.2. below) created an easy reference guide while minimizing language and literacy barriers.

Figure 9.2. Waste Segregation





To ensure minimum standards and best practices are put into practice, SCMS and other partners developed a training program for in-service and clinical on-site training, as well as information, education, and communication (IEC) materials.

SCMS conducted a pilot rollout at five VMMC clinical sites located in Mbeya, Mbozi, Shinyanga, and Simiyu. The focus of the pilot rollout was to introduce and assess the utility and applicability of the guide at VMMC sites. A total of 37 health care and medical waste personnel received technical guidance during the trainings.

These tools, when used in unison with the national standards, help implement behavior change and establish ownership of guiding principles, critical elements to the sustainability of proper management of HCW and environmental best practices. Currently, SCMS is in the process of generalizing these materials as part of the [SCMS VMMC Health Care Waste Management Toolkit](#).

CHAPTER 10.

Comprehensive Quality Assurance and Continuous Quality Improvement

GOALS

To ensure site staff are able to:

- Provide comprehensive, high-quality VMMC services at all sites, in line with national, WHO (World Health Organization) and PEPFAR (U.S. President’s Emergency Plan for AIDS Relief) standards through quality assurance and continuous quality improvement activities.
- Prioritize patient safety, maximize site-level efficiencies, and build capacity for implementation of quality methodology.

WHAT USERS NEED TO KNOW

Comprehensive quality systems encompass quality improvement/assurance (QI/QA) and external quality assessment (EQA) as well as continuous quality improvement (CQI) mechanisms. [See [WHO Male Circumcision Quality Assurance: A Guide to Enhancing the Safety and Quality of Services](#), [PEPFAR External Quality Assessment \(EQA\) Tools](#), and [USAID ASSIST Project VMMC CQI and EQA Toolkit](#)]. The development of a well-coordinated, comprehensive quality assurance and continuous quality improvement strategy is critical to the success of any health program scale-up plan (Massoud 2001). It is also important that this strategy is integrated into all aspects of the VMMC program right from the start of VMMC services. QA is a cross-cutting activity, linking other VMMC pillars, including leadership, management, infection control, waste management, and the VMMC minimum package of services. [See [WHO Male Circumcision Quality Assurance: A Guide to Enhancing the Safety and Quality of Services](#)]. Without a targeted strategy focusing on provision of high-quality VMMC services, patient safety and robust infection control practices, investments in VMMC service provision, and scale-up may not yield the anticipated results [See [WHO Male Circumcision Quality Assurance: A Guide to Enhancing the Safety and Quality of Services](#)]. Furthermore, the VMMC program may continue to be vulnerable to several unanticipated consequences, such as poor patient outcomes, high morbidity and mortality rates, and fear/stigma of the VMMC program, thereby potentially negating investments in demand-creation activities. [See [PEPFAR Quality Strategy](#)]. It is therefore important to ensure QA and CQI activities are prioritized during scale-up of VMMC programs and concerted efforts are made toward promoting integration, capacity development, routine quality monitoring, and implementation with a goal of sustainability [See [USAID ASSIST Project VMMC CQI Toolkit](#)].

FREQUENTLY REFERENCED INFORMATION

External quality assessment (EQA): EQA measures the extent of compliance to the minimum quality standards and performance against quality indicators and guidelines. It is often conducted by independent individuals or organizations using standard tools across a number of facilities, districts, provinces, and countries.

Continuous Quality Improvement (CQI): CQI is an integral part of how everyday services are performed. It ensures understanding of the systems and processes for doing work in order to identify any prevailing gaps. Since all activities contain two major components—what is done (content) and how it is done (process of care)—CQI is best achieved by addressing both of these components at the same time. This paradigm for QI makes organizations more efficient and able to provide quality care with increased access and decreased waste, often at less cost.

The difference between EQA and CQI: EQA is a periodic formal assessment carried out typically by outside experts to identify performance gaps against a set standard; whereas, CQI is an ongoing process, structured but potentially less formal, carried out by program staff to both identify and address inadequate performance against either external standards or their own insights to facilitate improvement.

FOR ADDITIONAL INFORMATION

Routine assessments (either internal or external) of quality should be a continuous and ongoing activity to ensure that any deviations from the expected level of quality are identified quickly and remedied. Country programs should reinforce the need for VMMC sites to conduct routine self-assessments of quality [See [USAID ASSIST Project VMMC CQI Toolkit](#)] on a given schedule and to implement CQI for VMMC services, as well as to facilitate EQA assessments [See [WHO Male Circumcision Quality Assurance: A Guide to Enhancing the Safety and Quality of Services](#) and [PEPFAR External Quality Assessment \(EQA\) Tools](#)]. It must be understood that, while EQA and CQI are separate activities, they are inextricably linked, comprising inherent synergies and latent potential (see Figure 10.1).

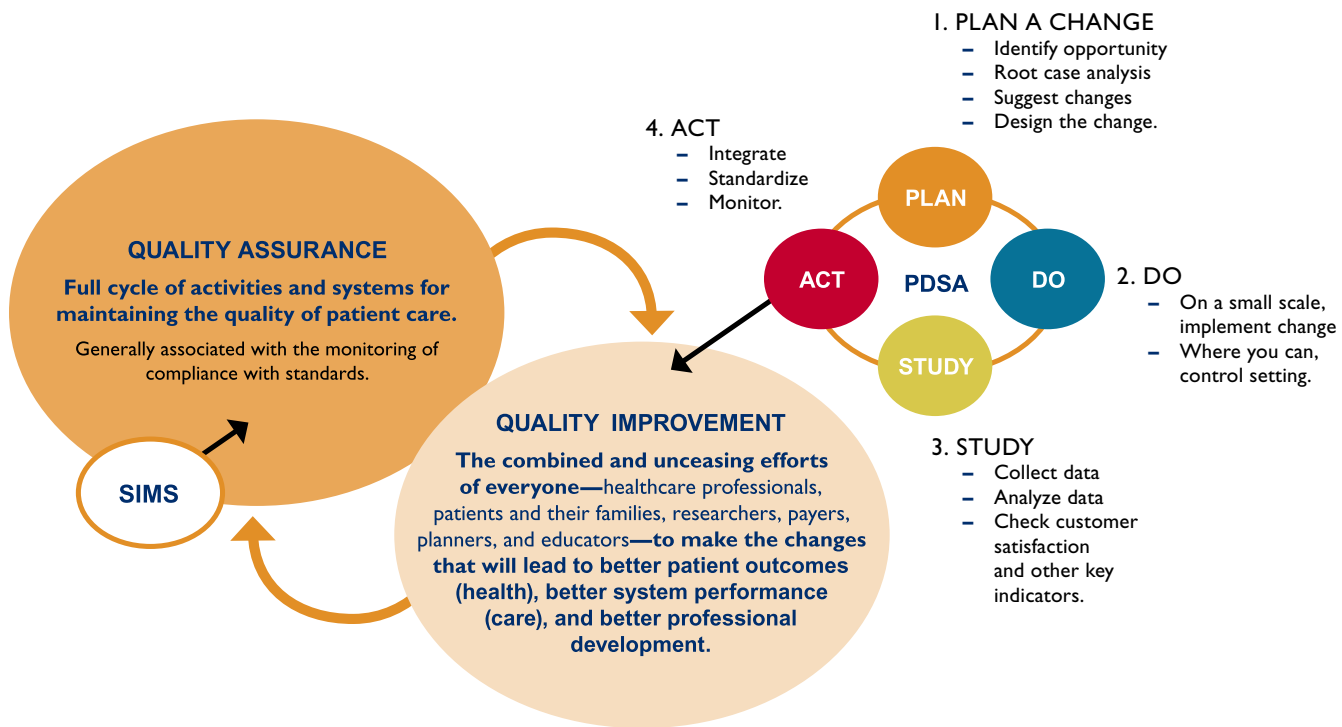
CQI involves a service provider-led iterative process of testing changes, initially on a small scale, through “plan-do-study-act” (PDSA) cycles, to develop solutions for the identified gaps. The series of steps to PSDA include plan a change, do, study, and act (see figure 10.1). Once the proposed solutions are proven, they are then spread to the entire system to yield better outcomes. This is essentially a supportive process, whereby sites are assessed to gauge the extent of compliance to the minimum quality standards, performance against quality indicators and guidelines, to note identified gaps, and to put into place and monitor remedial plans and actions. Subsequently, onsite mentoring and coaching are performed and reassessments are conducted on a regular basis. Primarily CQI is aimed at bridging the gaps between the expected level of care according to national, PEPFAR, and WHO VMMC standards and actual level of care currently provided by the VMMC service sites.

EQA assessments provide an opportunity for sites to improve their performance further and to identify areas needing support.

Routine CQI assessments should occur at least quarterly and EQA exercises at least annually. Both activities should occur more frequently if serious issues are identified. However, it is important to note that regular assessments on their own do not lead to improvement. Deliberate CQI efforts should be put in place to address any gaps identified through these regular assessments. The VMMC CQI assessment tool [See [USAID ASSIST Project VMMC CQI Toolkit](#)] should be revised and adapted annually to meet the needs of the program and to act on any new evidence related to client safety or changes in policy.

In addition, there is a requirement for all PEPFAR-supported sites to receive SIMS (Site Implementation Monitoring System) visits. All SIMS visits are conducted by PEPFAR personnel and are categorized as a subset of the overall QA activities within the VMMC program.

Figure 10.1. Relationship between EQA, CQI, and SIMS



Adapted from J. Amman, SIMS training Johannesburg, November 2014

VMMC EQA ACTIVITIES

The objectives of VMMC EQA assessment visits are to:

- Assure that all PEPFAR-funded VMMC service provision meets appropriate standards and best clinical practices.
- Monitor PEPFAR-funded VMMC service delivery programs by conducting QA assessments of implementing partners' service sites in resource-limited settings.
- Identify areas where technical assistance and support for program improvement is needed.
- Identify policy issues and quality gaps that relate to clients' safety that require immediate remedy.
- Build/strengthen the capacity of respective ministries of health (MOHs) to conduct VMMC QA.
- Review and identify potential system-wide barriers that may impede VMMC scale-up.

An EQA assessment typically takes three to four hours per site for a team of three to four assessors. It 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 [EQA Country Report Template](#) and [EQA Site Report Template](#)]. 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 they can easily be adapted to different local and health contexts.

VMMC CQI ACTIVITIES

The objectives of the VMMC CQI program are to:

- Ensure ongoing improvement within VMMC programs by identifying specific gaps and appropriate solutions which are then implemented at site level.
- Complement ongoing EQA findings to monitor PEPFAR-funded VMMC service delivery programs by conducting in-depth comprehensive baseline CQI reassessments of implementing partners' service sites.
- Ensure that all PEPFAR-funded VMMC service provision is in compliance with international appropriate standards and best clinical practices.
- Identify strengths, weaknesses, and best practices within the VMMC program.
- Build/strengthen the capacity of respective PEPFAR partners and MOH staff to conduct and sustain ongoing VMMC CQI programs.
- Promote shared learning between VMMC clinics, districts, provinces, and countries to quickly spread best practices.

The overall process of CQI includes an initial baseline assessment and feedback, followed by CQI team formation and onsite coaching and mentoring on an ongoing basis. To ensure steady progress, CQI reassessment visits should be conducted regularly, preferably every quarter. A CQI assessment (either baseline or reassessment), which is similar to an EQA visit, typically takes four to six hours per site, depending on the size of the assessment team and the services provided at site level. All CQI assessments should be conducted using standardized CQI tools aligned to the local policies and guidelines [See [VMMC CQI and EQA Assessment Toolkit](#)]. CQI assessments include direct observation of facility procedures and activities; staff interviews; review of material resource inventories; and review of policies, client registers, and records. Depending on the country, there are seven or eight key domains/ areas consisting of several standards identified for CQI in VMMC which must be observed for completion of an assessment visit. The main domains are: (1) Leadership and Planning; (2) Management Systems; (3) Monitoring and Evaluation; (4) Registration, Group Counseling, and IEC (information, education, and communication) Material; (5) Individual Counseling and HIV testing; (6) Infrastructure, Supplies, Equipment, and Environment; (7) Medical Circumcision Surgical Procedure (preoperative, intraoperative, and postoperative tasks including client follow-up); and (8) Infection Prevention and Control, including waste management.

Findings from the CQI assessments are summarized by overall and site-specific reports, including narrative sections as well as “VMMC CQI dashboards” indicating performance levels. [See [Uganda VMMC CQI Guide](#) and [USAID ASSIST Project VMMC CQI Toolkit](#)]. The overall report helps national and regional entities and MOHs to identify their programs' strengths and challenges and implement specific system-strengthening activities. Site-specific reports help national programs and local facilities develop interventions to solve specific problems and 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.

CASE STUDIES

Case Study 10.1. Continuous Quality Improvement in Uganda and South Africa

TOOLS, INSTRUMENTS & GUIDANCE DOCUMENTS

The following documents, which are available online and in the accompanying external media (included with the hard copy version of this Guide), provide the background information or procedural guidance used for development of this chapter.

1. WHO Male Circumcision Quality Assurance: A Guide to Enhancing the Safety and Quality of Services
2. PEPFAR External Quality Assessment (EQA) Tools
3. WHO Manual for Male Circumcision Under Local Anaesthesia, 1st edition
4. PEPFAR Quality Strategy
5. USAID ASSIST Project VMMC CQI and EQA Toolkit
6. EQA Country Report Template
7. EQA Site Report Template
8. Uganda VMMC CQI Guide

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ABBREVIATIONS

ASSIST	Applying Science to Strengthen and Improve Systems
CQI	continuous quality improvement
IEC	information, education, and communication
IPC	infection prevention and control
IQA/EQA	internal and external quality assessment
MOH	ministry of health
PDSA	plan-do-study-act
PEPFAR	U.S. President’s Emergency Plan for AIDS Relief
QA	quality assurance
SIMS	site implementation monitoring system
WHO	World Health Organization



CASE STUDY 10.I.

Continuous Quality Improvement in Uganda and South Africa

BACKGROUND

Quality improvement has been shown to be an effective tool for ensuring the safety and quality of VMMC services. This case study describes how quality and safety problems revealed in EQA were addressed through CQI, leading to improved adherence to VMMC quality standards, improved counseling and informed consent, and higher follow-up rates.

Figure 10.I.1. VMMC EQA Dashboard

Health unit	Baseline Feb-May 2013							Jan 14							Feb 15						
	Management systems	Supplies, equipment & environment	Registration group education and IEC	Individual counseling & HIV testing	Male circumcision on surgical procedure	Monitoring & evaluation	Infection prevention	Management systems	Supplies, equipment & environment	Registration group education and IEC	Individual counseling & HIV testing	Male circumcision on surgical procedure	Monitoring & evaluation	Infection prevention	Management systems	Supplies, equipment & environment	Registration group education and IEC	Individual counseling & HIV testing	Male circumcision on surgical procedure	Monitoring & evaluation	Infection prevention
1	80	50	80	80		80		70	83	67	100	91	86	91	88	100				85	100
2	80	80	80	80		80	92	80	67	75			87	92	80	67	80			87	92
3	80	83	80			80	94.6	80	67	100			93	100	90	100	83	80	90	78	92
4	80	50	80			80	82	90	83	83	83	88	92	100	90	83	100	100	100	93	100
5	80	80	80			80	80	80	67	83	100	88	88	86	100	100	83	100	100	86	100
6	80	50				80	70	90	83	100	100	100	93	93	100	100	100	100	100	100	92
7	80	50	50			75	60	70	83	67	83	82	86	89	90	83	100	83	100	92	96
8	50	50	80			80	77	90	100	83	100	90	86	85	90	100	83	100	90	86	85
9	60	50	83	80	64	75	92	90	100	100	82	100	100	100	100	83	100	100	100	86	100
10	80	50	50			80	80	90	100	100	83	100	92	83	100	100	100	100	90	100	92
11	80	80	80			80		80	100	100	88	90	77	75	80	80	83	90	80	100	88
12	80	80	80			80	70	100	83	100	80	83	106	82	100	83	100	80	83	100	92
13	60	67	75	83	81	80	80	90	67	83	100	100	86	100	80	83	100	100	100	86	83
14	70	50	80			50	80	100	83	100	100	100	93	100	90	83	100	100	100	86	83
15	60	83	80			50	90	100	84	67	100	82	67	100	100	84	100	100	97	86	93
16	80	67	100			80	58.3	100	100	100	100	100	100	100	90	83	100	100	100	93	100
17	80	83	75	100	100	80	84.6	90	83	100	100	100	100	92	100	67	100	83	100	86	92
18	70	67	100	67	100	69	75	100	67	100	100	100	100	75	100	75	100	100	100	100	80
19	80	50	80			80	100	100	83	83	100	97	100	100	100	83	83	83	80	97	100
20	60	50	80			72	92	100	83	83	83	85	93	85	100	83	83	83	85	93	85
21	70	50	80			80	77	90	67	83	84	77	100	76	90	80	83	84	80	75	83
22	80	83	100			93	100	90	100	100	100	100	100	100	90	100	100	100	90	85	100
23	70	100	100	100	100	93	100	90	84	100	100	100	100	100	100	83	100	83	97	86	100
24	70	100	100	100	100	93	100	90	100	100	100	100	93	100	100	83	100	84	100	86	92
25	60	50	100			80	100	90	83	50	83	82	50	77	90	83	100	100	91	86	85
26	60	83	50			80	76.92	90	67	84	100	86	79	92	100	67	100	100	91	93	92
27	80	83	75	100	100	75	100	90	84	100	100	91	86	100	90	83	100	100	91	79	85
28	80	50				78	80	90	75	50	84	87	83	70	90	75	50	84	87	83	90
29	80	67	67			80	86	90	67	67	83	80	93	82	90	83	83	100	91	93	92
30	80	67				80	84.6	90	67	83	100	91	93	82	90	67	83	83	70	100	100

Initial work in Uganda: In 2012, two EQAs found serious quality gaps, including lack of standardized registers, poor documentation of client informed consent, lack of emergency preparedness, and untrained providers. In response, ASSIST (Applying Science to Strengthen and Improve Systems) helped form improvement teams to identify barriers in achieving national standards, identify solutions (changes) to overcome the barriers, and test these changes, while collecting performance data to measure whether gaps were bridged. A color-coded dashboard based on compliance with 53 standard categories was used by teams to measure progress. Site staff came together for periodic peer-to-peer learning sessions to share best practices. Within less than a year of carrying out CQI, the majority of sites had achieved “green” (good) performance across the majority of the standards, and these results have been sustained into 2016, except for in dropped sites where the ASSIST program was not giving external support to the sites.

Introduction in South Africa: Baseline assessments were conducted at 127 sites across the country, and then a smaller group of sites were identified as needing “intensive support” to form site-level teams. These teams worked to develop and implement site-level improvement plans, empower those teams to identify gaps in service delivery, test changes to address those gaps, and use their own data to monitor improvements in quality. Two cross-provincial learning sessions were conducted to share learning across sites and provinces and to identify successful site-level changes and best practices for scale-up. In under a year, significant improvement was achieved across all eight quality standards in the intense-support sites, as highlighted in Figure 10.1.2.

Figure 10.1.2. VMMC CQI Dashboard

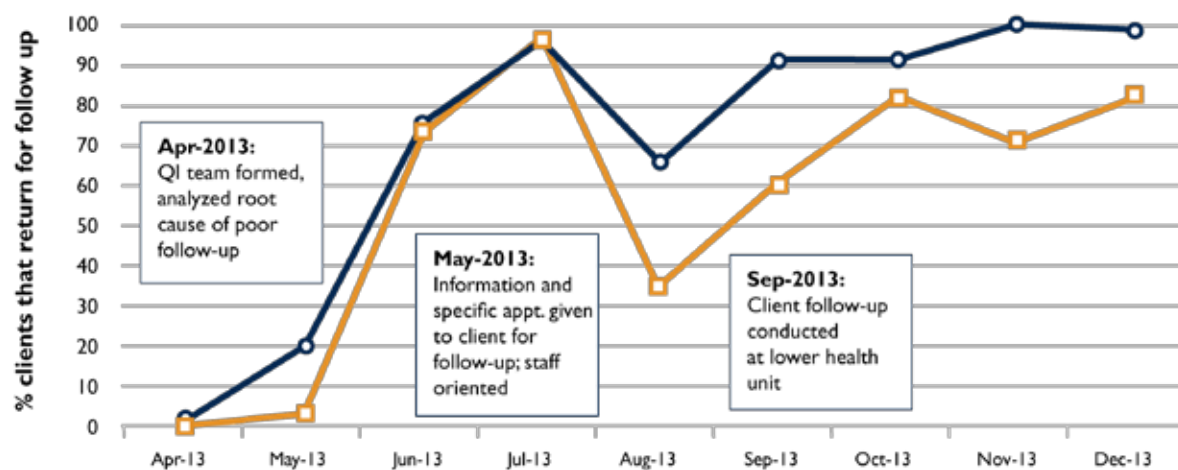
	Baseline (June-September 2014)									First re-assessment (Feb-May 2015)									Second re-assessment (Aug-Sept 2015)							
	Average of Leadership	Average of Management	Average of M&E	Average of Group	Average of Individual	Average of Infrastructure	Average of Surgical	Average of Infection-	Sum of A-0	Average of Leadership2	Average of Management 2	Average of M&E2	Average of Group2	Average of Individual2	Average of Infrastructure2	Average of Surgical2	Average of Infection-2	Count of R -2	Average of Leadership3	Average of Management 3	Average of M&E3	Average of Group3	Average of Individual3	Average of Infrastructure3	Average of Surgical3	Average of Infection-3
Quality Standard																										
Average across all sites	40.5	68.5	74.2	84.2	81.6	75.6	74.5	78.2	0.0	60.1	83.4	79.6	88.5	84.8	93.8	89.5	92.1	43.0	74.9	92.1	86.0	92.0	91.5	96.7	94.0	95.7

QUALITY IMPROVEMENT INTERVENTIONS AT INDIVIDUAL SITES

Using similar approaches, ASSIST has worked with individual sites to improve the quality of VMMC services, which include the following:

- Gulu Regional Referral Hospital in Uganda improved 48-hour client follow-up from initially only 2 percent in April 2013 to 99 percent. The follow-up rate at 7 days was also noted to be good at 82 percent as shown in Figure 10.1.3.
- A large private provider in Johannesburg was supported to establish a CQI team to address infection prevention and control (IPC) and waste disposal. Within eight months, the clinic improved its IPC score from 66 to 98 percent and has made the new practices part of routine VMMC service provision.
- A rural primary health care center in South Africa formed a CQI team including both Department of Health and implementing partner staff that mobilized the site staff to standardize preoperative history-taking and examination, repair infrastructure, increase privacy, upgrade staff skills in IPC and counseling, and empower mobilizers. Within 11 months, scores for surgical procedures improved from 60.6 to 96.8 percent and for IPC from 72.7 to 95.3 percent. The number of VMMC procedures performed increased from 60 to 124 per month (January–June 2015). The CQI team integrated changes into routine service provision.

Figure 10.1.3. Time Series Chart of Service Improvements



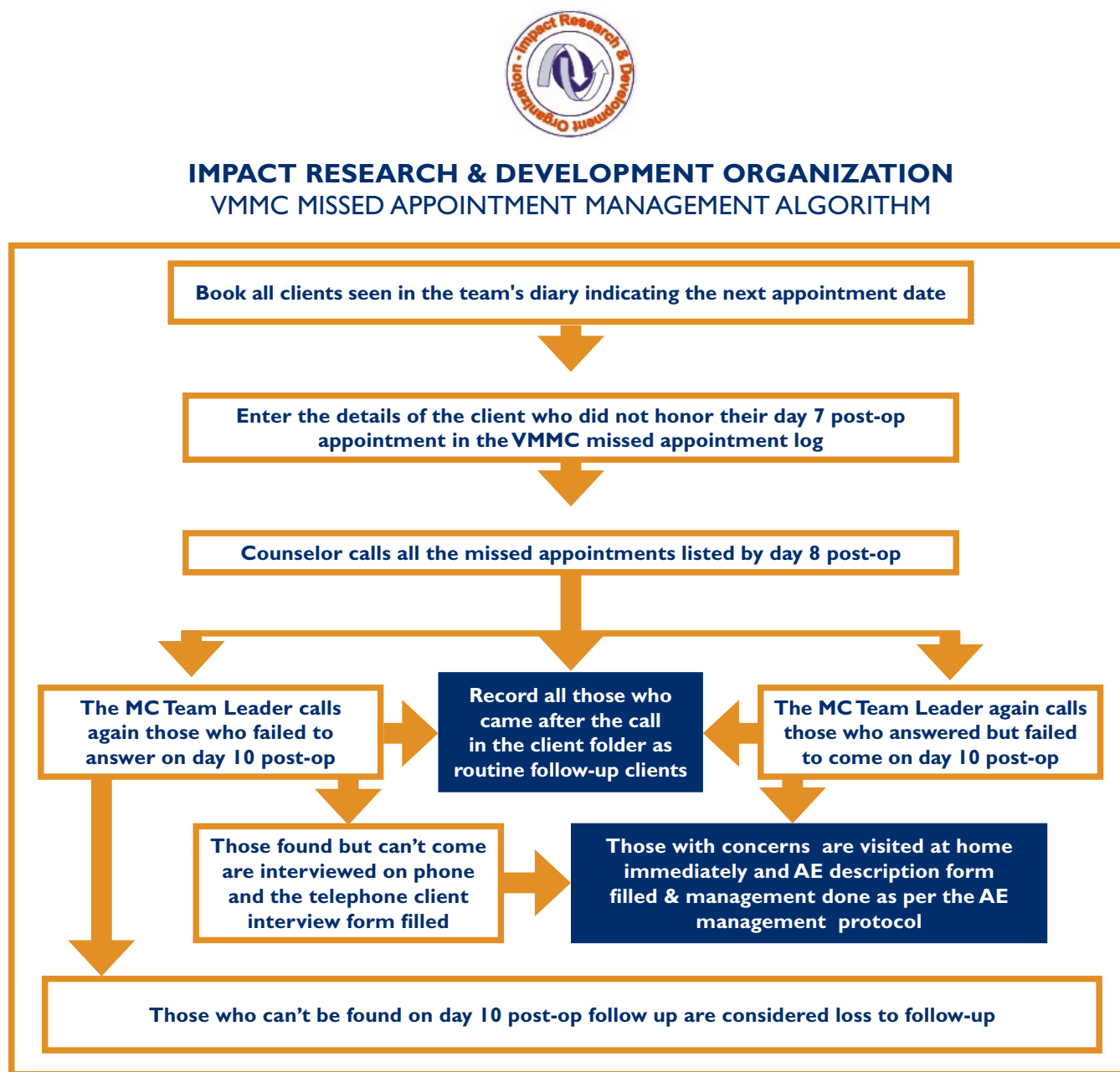
	Apr-13	May-13	Jun-13	Jul-13	Aug-13	Sep-13	Oct-13	Nov-13	Dec-13
—●— % age FU 48 hrs	2	20	76	97	66	91	91	100	99
—□— % age FU 7 days	0	3	74	97	35	61	82	71	82
# Return 48 hr	1	27	32	773	71	69	31	77	470
# Return 7 days	0	4	31	766	38	46	28	55	388
# Circumcised	46	134	76	793	108	76	34	77	473

LESSONS LEARNED

- The Uganda VMMC CQI pilot demonstrated that site teams could be mobilized to significantly improve VMMC service quality. Broad consultation with stakeholders was vital at start-up to engage MOH and IPs. Use of simple but informative tools such as the dashboard was key.
- Implementation of CQI initiatives in VMMC programs requires patience and perseverance, but also yields tangible results. Capacitating and involving all staff in ongoing CQI initiatives allows for creativity, team work, increased staff motivation, and optimized service delivery.

IMPROVEMENTS TO POST-OPERATIVE CLIENT FOLLOW-UP THROUGH THE DEVELOPMENT OF TRACKING TOOLS

Figure 10.1.4. VMMC Missed Appointment Management Algorithm




Between 2010 and 2013, the VMMC client post-operative follow-up rate at all VMMC sites operated by Impact Research and Development Organization (IRDO) in 10 counties in eastern Kenya ranged from 29 to 32 percent. In November 2014, the team designed a follow-up system flow chart (Figure 10.1.4) indicating the steps to take if a client misses follow up, and a Missed Appointment Log (Figure 10.1.5) to record those who miss their appointments and to document the outcome of follow-up calls made.

Figure 10.1.5. Follow-Up Missed Appointment Log

VMMC Follow-Up Missed Appointment Log

No.	Date of Missed Appointment	Client No.	Real Name	Age	Phone #	Date Called	Called By	Outcome
						Call 1		
						Call 2		
						Call 1		
						Call 2		
						Call 1		
						Call 2		
						Call 1		
						Call 2		
						Call 1		
						Call 2		
						Call 1		
						Call 2		
						Call 1		
						Call 2		
						Call 1		
						Call 2		
						Call 1		
						Call 2		



After surgery, clients are issued a card indicating the return date and reminded to return for postoperative review on day 7, as per VMMC Kenya's policy. Those who miss follow-up on day 7 are recorded in the VMMC Follow-up Missed Appointment Log. If on day 8 the client has not come for review, the team leader advises the counselor to call the client. If by day 10 the client still has not honored the appointment, the team leader makes a second call. If the client comes after the day 8 or day 10 telephone reminder, he is recorded on the client folder as routine follow-up.

However, if the client is found on the day 10 telephone call but unable to come for review, the clinician will interview the client over the phone and complete a client telephone interview form. If issues of concern are identified, the team leader visits the client at home or in a nearby health facility for review. If the client is not reached on the day 10 telephone call and tracking through the mobilizers also fails, he will be considered lost to follow-up.

These efforts have seen an increase in follow-up rates, from an average of about 30 percent in 2010–13, to 38 percent in 2014, and to 59 percent in early 2015, nearly doubling the client postoperative follow-up rate in two years.





CHAPTER II.

Geographic Information Systems (GIS)

CHAPTER GOALS

To ensure implementing partners and site-level staff are able to use GIS technology to:

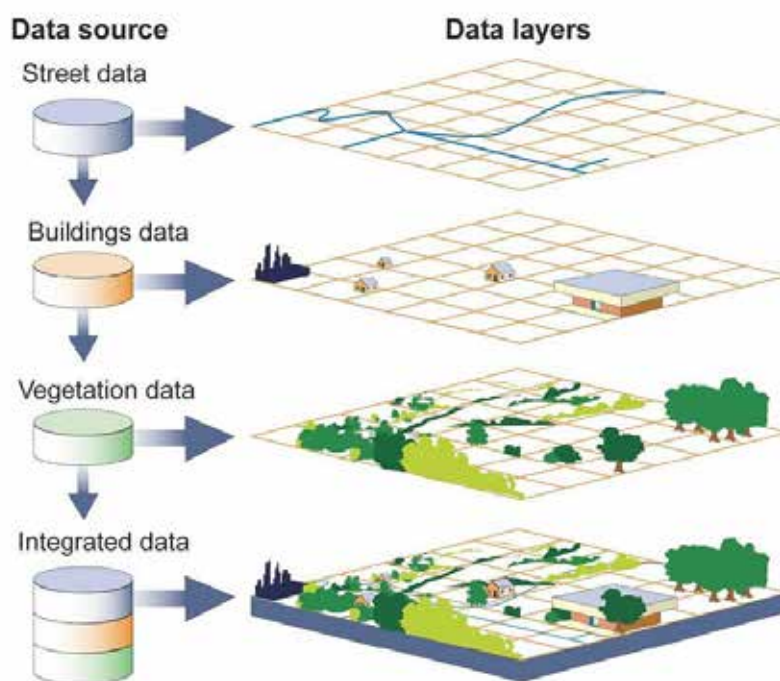
- Efficiently locate and schedule voluntary medical male circumcision (VMMC) services to improve VMMC uptake by males in communities
- Adequately match VMMC services to priority geographic areas and priority male age groups.

WHAT USERS NEED TO KNOW

WHAT IS GIS?

A **geographic information system (GIS)** is a computer system for capturing, storing, checking, and displaying data related to positions on the earth's surface. One of the advantages of GIS is its ability to support the analysis and display of multiple datasets and data types in one place. Each dataset is referred to as a layer (see Figure 11.1). This unique capability enables users to visualize, question, analyze, and interpret data to understand relationships, patterns, and trends [See [ESRI website, What is GIS?](#)].

Figure 11.1. GIS Displays Multiple Datasets in Layers



Source: GAO

In public health programs, GIS allows for a synthesis or layering of multiple types of data, such as infrastructure, human resources, and health and population data. GIS is increasingly used in public health in an effort to increase efficiency in program planning (Gammino 2014). Using GIS the Tanzania VMMC program reached more men in previously underserved rural areas and improved coverage from 48 percent in 2011 to 93 percent by the end of 2014 (Mahler et al. 2015). This chapter provides a brief review of GIS and how it can be used to improve VMMC program efficiency, citing case studies and other GIS resources.

ADVANTAGES OF USING GIS TO TARGET PROGRAMMING

GIS is becoming an essential tool for public health professionals to plan effective and efficient program delivery strategies. Specifically, GIS can be used to provide decision support by leading to new insights that guide the understanding of health needs and program planning and implementation.

Applied in the health context, spatial analysis of GIS data can shed light on many health system questions, such as the proper allocation of community health workers in the surrounding population; the organization of the referral network based on characteristics such as health facility location and number and types of staff; and factors affecting service uptake such as the surrounding geography (for example, the proximity of mountains and rivers).

Using GIS to layer population data with health statistics is not new, but using GIS to view and synthesize multiple types of data in relation to each other—such as infrastructure, human resources for health, health statistics, and population data—to inform health service delivery is an innovative strategy that has rarely been applied.

In the VMMC program, GIS can help plan and forecast VMMC activities such as campaigns and outreach services. With information from a GIS database, program managers can select sites, plan routes, and work out anticipated challenges in terms of resource needs. To facilitate this analysis, datasets including health and administrative data must be collated into a database and geocoded so that they can be linked geospatially on maps. Once a database and system are in place, users can retrieve information about a particular site or community with one click on an interactive map, and they can use that information for planning services. In settings where there is no existing GIS database, program managers will have to collect all the information required in order to establish the database. For example, the information required may include GPS coordinates, maps, pictures, road networks, and facility staffing levels, among others. For additional information and resources related to data requirements see the section “For Additional Information.”

FREQUENTLY REFERENCED INFORMATION

Many software systems can be used for GIS, ranging from ones that are free and open source to those that are expensive and require a license. Using GIS does require some technical capacity and experience with the software. Popular GIS software products include:

- ArcGIS by Esri: <https://www.arcgis.com/features/index.html>
- QGIS: <http://www.qgis.org/en/site/>
- Carto: <https://carto.com/>
- Project SOAR Geographic Information System Dashboard for VMMC in South Africa and Tanzania: <http://www.popcouncil.org/research/supporting-operational-aids-research-project-soar>.

FOR ADDITIONAL INFORMATION

READY-TO-USE VMMC GIS DASHBOARDS AVAILABLE TO PROGRAM MANAGERS IN SOUTH AFRICA AND TANZANIA

Many countries have not yet benefitted from this approach due to funding, technical capacity, or data access/sharing constraints. To bring the power of GIS mapping to VMMC program implementers without the need for formal GIS software or technical capacity, a user-friendly VMMC GIS Dashboard is being developed under USAID's Project SOAR (Supporting Operational AIDS Research). The dashboard is an online tool that enables easy integration, visualization, and mapping of a country's VMMC program data. Its prebuilt architecture pulls data from existing sources, including DATIM, DHIS, and the DMPPT 2.1 model, and allows partners to import indicators not reported at the national level. Users of any technical level can easily access and map program data, examining trends to determine where efforts are needed most. By drawing upon existing systems and enabling one-click mapping, the dashboard provides a cost-effective and comprehensive solution for countries looking to use mapping to improve VMMC programs.

Coverage estimates from the dashboard's online tool can be mapped geographically, either alone or layered with other available data, such as population, HIV prevalence, health facility locations (both national and PEPFAR-supported) or transport routes. This can aid in the planning and implementation of demand generation activities. For example, if the online tool shows that MC coverage is low among 15–24 year olds in a particular district, a partner can use the GIS dashboard to determine how and where to implement a mobile clinic or outreach campaigns for youth in that district. S/he could examine the road infrastructure or other potential barriers to access that might affect program planning and can also see whether other partner facilities exist nearby.

The dashboard also serves as a data quality monitoring tool by comparing different indicators across different data sources. With the ability to visualize the same data provided by different sources, data quality issues can be identified and discussed to find an appropriate remedy.

Finally, in consolidating and mapping key VMMC indicators across data systems (e.g., government and PEPFAR facilities) the dashboard serves as a “one stop shop” for key VMMC program data. Implementing partners can also create their own indicators and upload corresponding datasets specific to their program needs. This offers a more comprehensive picture of a country's program, allows for a shared understanding of progress toward targets, and facilitates coordination and strategic planning between partners as demand creation efforts are rolled out.

GETTING STARTED WITH GIS

For those new to the use of GIS, and in countries where ready-to-use dashboards are not available, the Global Health eLearning (GHeL) Center offers a free introductory course online called, “[Geographic Approaches to Global Health](#).” This course provides an overview of geographic data, often referred to as spatial data, and their utility in decision making related to health program implementation.

Once foundational knowledge of GIS is acquired, one must identify a series of questions that can help guide resource allocation, as well as a process for answering them. To aid program managers, MEASURE Evaluation provides guidance on how to use GIS to inform resource allocation decisions specifically for facility-based health services [See [Using Geospatial Analysis to Inform Decision Making in Targeting Health Facility-Based Programs: A Guidance Document](#)]. MEASURE Evaluation identifies the following sequence of questions to be

answered in a geospatial analysis of health facility access:

1. Where are existing services currently located?
2. Where is there eligible population that does not have access to the service?
3. How should future investments in facility-based services be allocated?

Question 1: Where are existing services located?

To answer this question requires data on the health service environment. Details on the distribution and capacity of facilities to offer services can provide information related to the supply of a service. Additional supply-side data points might include cost, availability of trained staff, access to technical inputs like water and electricity, etc.

Question 2: Where is the eligible population that does not have access to the service?

To maximize the impact of investments in facility-based services, program managers must identify the locations of the population with the greatest need. Data on the target population is essential for identifying existing health coverage and access, as well as gaps in service for the population in need. Accordingly, it is essential to gather data on the distribution, size, and need of the population the program intends to serve. This information serves as the demand side for services. Additional information that could be included to understand the demand side might include cultural preferences or potential clients' perception of cost.

Question 3: How should future investments in facility-based services be allocated?

Next, the answers to questions 1 and 2 must be brought together in order to determine where facility-based services can achieve the greatest impact. Because true impact may prove difficult to measure or forecast, it may be preferable to rely on performance indicators such as service utilization or coverage rates.

The use of GIS can best help assess the physical accessibility aspect of coverage. To do that, the two types of data mentioned under questions 1 and 2 must be linked through geographic, or spatial, data. Relevant spatial data will provide a context to the physical location and physical accessibility of services in relation to the population in need. Data of this kind might include roads and other transportation routes along with attributes that describe them, like type (paved or unpaved) and condition. Features of the terrain, like mountains or rivers, can also aid in understanding potential transportation barriers.

In Using Geospatial Analysis to Inform Decision Making in Targeting Health Facility-Based Programs: A Guidance Document, MEASURE Evaluation provides flowcharts to guide users through the choices that will need to be made in order to combine the aforementioned data, and analyze the geographic distribution of coverage gaps. The guide also provides an illustrative example, which walks through all three questions using a scenario on access to antenatal care in Namibia.

CASE STUDIES

Case Study 11.1. Use of GIS to Improve Demand for VMMC Services

TOOLS, INSTRUMENTS & GUIDANCE DOCUMENTS

The following documents, which are available online and in the accompanying external media (included with the hard copy version of this Guide), provide the background information or procedural guidance used for development of this chapter.

1. [WHO: Creating a Master Facility List](#)
2. [Using Geospatial Analysis to Inform Decision Making in Targeting Health Facility-Based Programs](#)

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ABBREVIATIONS

GHeL	Global Health eLearning Center
GIS	geographic information system
MC	male circumcision
MCHIP	Maternal and Child Health Integrated Program
QGIS	Quantum GIS
SOAR	Supporting Operational AIDS Research
VMMC	voluntary medical male circumcision





CASE STUDY II.I.

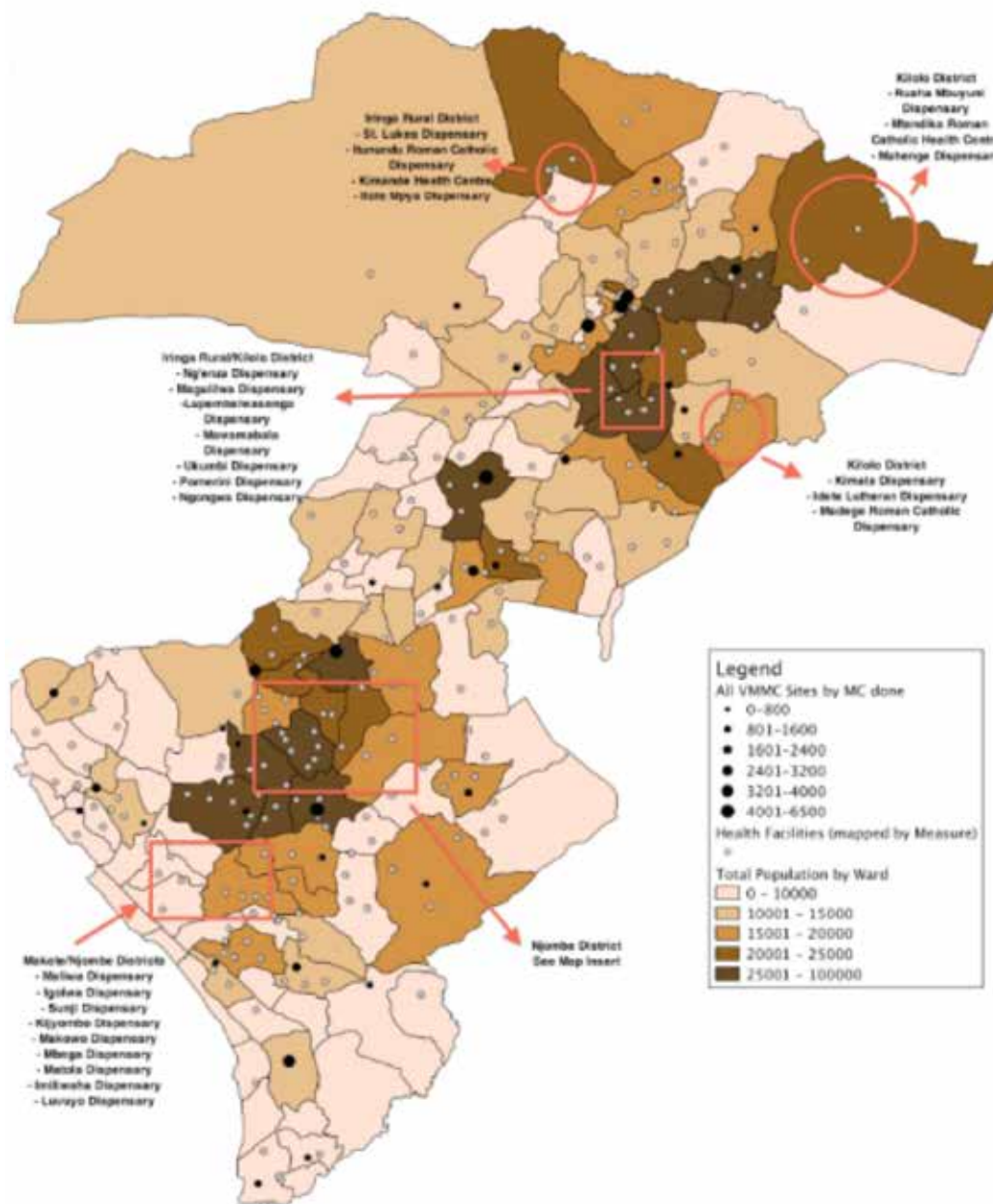
Use of GIS to Improve Demand for VMMC Services

In 2010 Tanzania began using high-volume VMMC campaigns to increase male circumcision coverage. As part of the strategy to continuously increase uptake of VMMC Services, adaptation and investment in campaign planning and implementation was required to maintain and improve campaign efficiency. Starting with the 2012 annual campaign, MCHIP (Maternal and Child Health Integrated Program) pioneered the use of GIS to efficiently allocate resources to VMMC campaign sites. In conjunction with other advances in campaign operations and service delivery, GIS was successfully used to increase the number of clients reached during campaigns.

Using open source tools (Quantum GIS [QGIS] and Open Layers), the team overlaid 2002 census data with geo-referenced health facilities information, administrative boundaries, and VMMC routine data. Thus they were able to make maps of facility locations, population concentrations, and locations where voluntary medical male circumcisions had already been provided. These maps helped MCHIP to identify areas in both regions with high concentrations of potential clients for VMMC. As a result, 24 outreach sites for the winter campaign were selected in 2012 with a catchment population of more than 5,000 males aged 10-49 years. Thus the program was able to serve 25,816 males in six weeks compared to 14,476 done over the same timeframe the previous year.

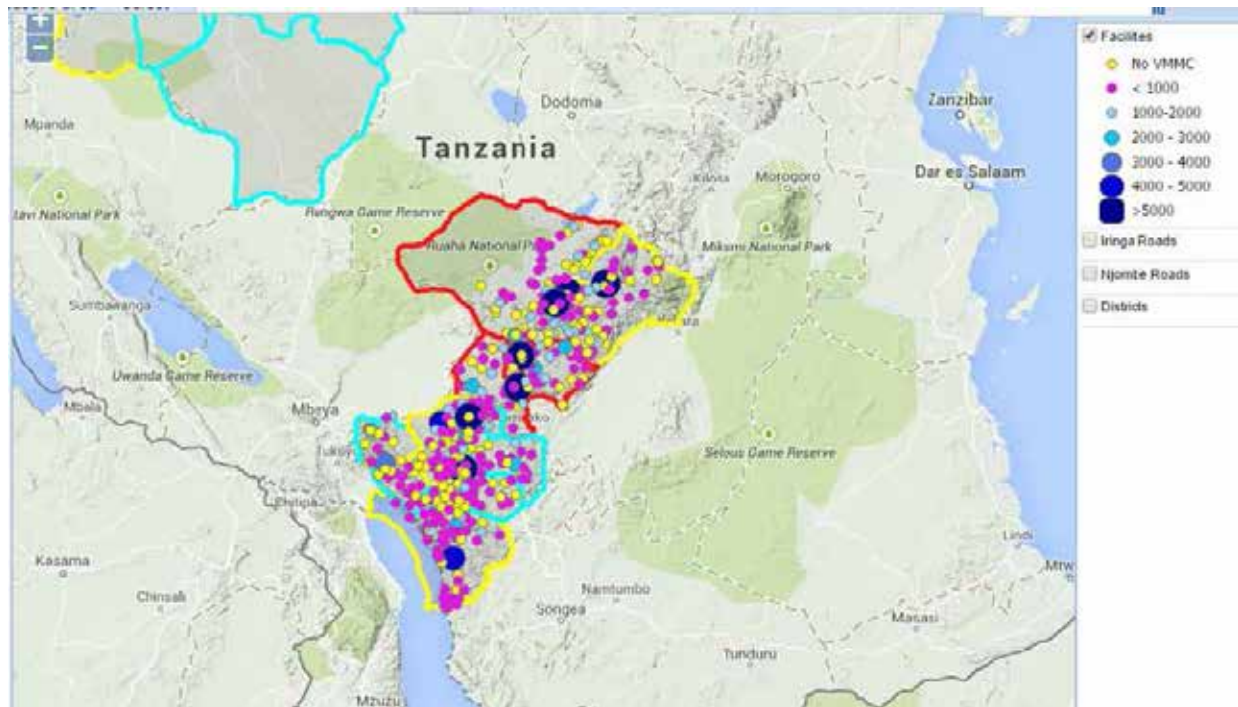
Early indications suggest that use of GIS will not only help to streamline the provision of VMMC services, but that it also has the potential to revolutionize health service planning and delivery for other essential health services once comprehensive facility data are in place. The system is currently being considered by the Tanzania National AIDS Control Program to assist in scale up of VMMC services nationally, and the GIS and facility data are being shared with regional authorities for use by other health programs.

Figure 11.1.1. Facilities and Potential Sites in Iringa and Njombe Regions for the 2012 Winter VMMC Campaign



Source: MCHIP/Tanzania GIS database

Figure 11.1.2. Map of Health Facilities in Iringa and Njombe Regions



Source: MCHIP/Tanzania GIS database

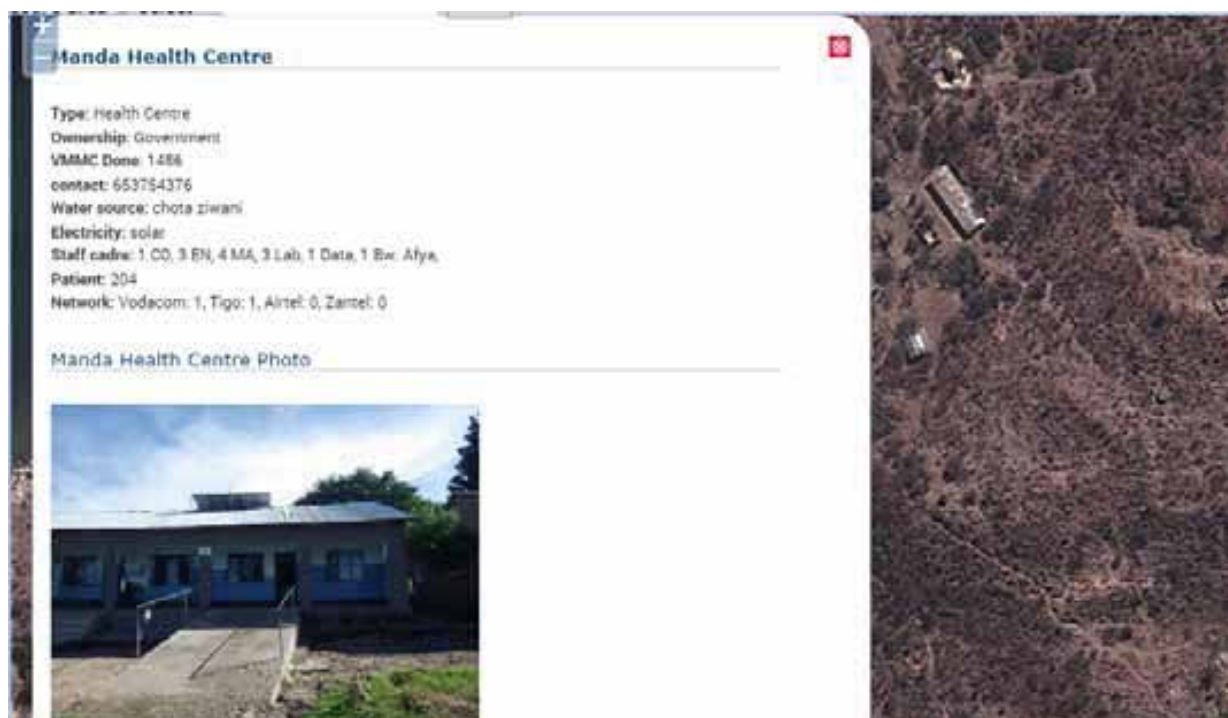
Figure 11.1.3. Satellite Image of Area Around Manda Health Center, Njombe Region



In the satellite view one can zoom in to see the facility and the surrounding area, thus giving a sense of the community being served based on how households are dispersed and the ease of access to the facility by looking at the road networks. One can also estimate where demand creation activities for the facility could take place.

Source: MCHIP/Tanzania GIS database

Figure II.1.4. Satellite Image and Site Information, Manda Health Center, Njombe Region



This is a satellite image but showing a pop out window of the Manda Health Center. The details and characteristics of the Facility pops out in the window—showing type of facility, ownership, # VMMCs done, contacts, water source, electricity, staff cadre network coverage.

Source: MCHIP/Tanzania GIS database



CHAPTER 12.

Voluntarism & Informed Consent

CHAPTER GOALS

To ensure site-level staff are able to:

- Provide accurate and comprehensible information to male clients, spouses of male clients, and guardians of minors seeking VMMC (voluntary medical male circumcision) services to help them make informed decisions.
- Obtain and document the informed consent of males (and guardians of minors) seeking VMMC services.
- Ensure clients are aware of and comprehend the risks and benefits of VMMC and that they choose the services voluntarily and without coercion.

WHAT USERS NEED TO KNOW

SUMMARY

This chapter presents the requirements of the voluntarism and informed consent (IC) process. Specifically covered are the following topics: training site staff on elements and principles of the IC process, administering and documenting IC while ensuring that clients understand the risks and benefits as well as all other information on VMMC procedures, and proper wound care practices. The chapter also discusses issues relating to parental consent and assent for minors, the national age of consent, the role of parents/guardians, obtaining consent from illiterate participants, national policies, international guidelines, and PEPFAR (U.S. President's Emergency Plan for AIDS Relief) considerations [See [UNAIDS Safe, Voluntary, Informed Male Circumcision and Comprehensive HIV Prevention Programming Guidance for Decision-Makers on Human Rights, Ethical and Legal Considerations](#) and [PEPFAR Technical Considerations for COP/ROP 2016](#)]. Finally, two case studies are featured: one from Zambia evaluating clients' comprehension of key concepts, social norms, and practices regarding IC and the other from Uganda on successful use of the IC process to improve the quality of VMMC services [See [Evaluation of the Informed Consent Process for Male Circumcision Scale-Up in Zambia](#)]. The chapter cites and refers the reader to many resources for additional reading.

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 the appropriate ways to obtain it. 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 (have reached the legal age of consent) are able to give their own informed consent.

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 they should provide assent for the VMMC procedure. Those too young to understand the male circumcision procedure and provide assent, or who refuse 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 a guardian, including providing them (parents/guardians) with 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.

PEPFAR policies follow local laws about consenting clients for VMMC such as age of consent, in cases where some minors under 18 years may consent for VMMC or where school representatives such as head teachers may consent on a minor's behalf. Minors need to be accompanied when they seek VMMC services, and parents or guardians are advised to participate in all information sessions to ensure they understand the procedure very well and are able to apply the acquired information during wound care. The informed consent process should be conducted in a language that is understood by the VMMC client and his parent or guardian, as necessary.

ILLITERATE CLIENTS

Clients who are illiterate and therefore cannot sign the informed consent document should be provided the same information as other clients, including having the informed consent read to them. Their name and date should be well printed on the form and close to their thumbprint.

PEPFAR's annual VMMC Technical Considerations also recommend obtaining and documenting an adult informed consent and assent/parental consent for all minors before the VMMC procedure [See [PEPFAR Technical Considerations for COP/ROP 2016](#)]. Although obtaining the written informed consent form is performed once, informed consent is actually a process that must continue throughout the duration of the procedure. Staff therefore must ensure that not only does the client offer his signature/thumbprint (or her signature/thumbprint in case of female parents of minors) on the informed consent document, but also that his continued participation to receive the procedure is still acceptable at every step of the process. All information shared with clients and across sites needs to be consistent. This information should be incorporated into a standard operating procedure, and all site staff should be well versed in appropriate information about risks and benefits of VMMC, the VMMC procedure, pre- and post-op care, HIV, sexually transmitted infections (STIs), and so on.

ELEMENTS OF INFORMED CONSENT FOR VMMC

Obtaining informed consent is a process, not just a signed document. Informed consent should include the following elements [Modified from Code of Federal Regulations - 45 CFR 46.116(a) and 21 CFR Part 50.25(a)]:

- Purpose and average duration of the procedure and a description of the procedure to be followed such as the type of VMMC (surgical or device and which specific one will be used on the client).
- Explanation that male circumcision is permanent.

- Explanation that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the client is entitled, and that the client may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- A description of benefits to the client or benefits beyond the client such as indirect protection for women, reduced overall HIV transmission if more men get circumcised, and so forth.
- A description of any foreseeable risks and discomfort to the client.
- A description of recommended post-care procedures and schedules for follow-up visits.
- A statement describing to what extent the client's confidentiality and privacy of both their records and the procedure itself is maintained.
- An explanation that VMMC can be obtained at any time and a list of alternative places where it is provided under similar or different conditions.
- Whom to contact (including phone contact and physical location) for answers to pertinent questions about the VMMC, or the VMMC minimum package of services, or in case of complications.
- Confirmation that the client understands the key information.
- Time for questions and answers.

VMMC programs and sites should not deny rights or benefits to those who do not accept VMMC, as this could pressure them into accepting VMMC services. For example, a program should not deny a person access to HIV testing services, antiretroviral therapy, or condoms if they refuse VMMC services [See [UNAIDS Safe, Voluntary, Informed Male Circumcision and Comprehensive HIV Prevention Programming: Guidance for Decision-Makers on Human Rights, Ethical and Legal Considerations](#)].

FREQUENTLY REFERENCED INFORMATION

GIFTS, REIMBURSEMENTS, AND INCENTIVES TO CLIENTS

Paying Clients

Paying clients or providing incentives (in money or material goods) to undertake VMMC is not permitted under any circumstances in order to avoid coercion or the appearance of coercion. Any authorized reimbursement of money or goods given to clients must be used cautiously in line with the following considerations.

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 ministry of health 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 would not distort any existing national schemes.

STAFF COMPENSATION

Mobilizers

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. For example, mobilizers should be monitored to ensure that they do not give t-shirts or other gifts only to VMMC acceptors; instead gifts should be given to all people interested in VMMC or all people attending a certain mobilization event.

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. Instead PEPFAR programs are required 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 from an individual mobilizer referring a particular client. Mechanisms that further minimize perceived or actual rewards on a per-client/per-mobilizer basis are encouraged.

Site Staff

Clinicians who work overtime to provide VMMC services may be compensated for their time at a scale consistent with national standards. However, clinicians must not be compensated on a per-circumcision 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 for mobilizers is prohibited because it can lead to possible coercive practices. For the site, estimated targets should be used for planning and evaluation purposes only (e.g., order estimates for commodities, staffing levels, number of outreach sites needed, or site and staffing efficiency). Site or district level targets need to be monitored carefully to ensure that they do not flow down to individual service providers or peer mobilizers.

To ensure voluntarism and informed consent, programs should not only provide appropriate informed consent for clients, but should also comply with the following:

- Adhere to PEPFAR indicators and standards that need to be assessed during external quality assessment (EQA), site improvement and monitoring systems (SIMS), and continuous quality improvement (CQI) to monitor consent delivery and guarantee client comprehension, evaluate for coercive activities, and review reimbursement procedures [See Chapters [8](#) and [10](#)].
- Avoid practices outlined above that can be perceived to be coercive.
- Give special consideration to the needs of children and adolescents.

To evaluate the quality of informed consent provided to clients at VMMC sites, the Population Council assessed the clients' comprehension of key concepts and social norms and practices regarding informed consent for adolescents, analyzing the clients' experience versus their expectations [See [Evaluation of the Informed Consent Process for Male Circumcision Scale-Up in Zambia](#)]. Clients' understanding of messages was found to differ across clients, with most clients understanding benefits more than risks. The study team recommended separation of consent from clinical record forms and advised discreet informed consent form documents that can be read to and given to clients. This chapter includes a draft sample informed consent document. This is available as a template, though adaptation is necessary to align with local regulations.

FOR ADDITIONAL INFORMATION

SAMPLE INFORMED CONSENT FORM:

Voluntary Medical Male Circumcision (VMMC) for HIV Prevention

Client Consent to Participate in VMMC

I _____ (name(s) of staff administering informed consent) working for

_____ (name and address of site/organization) will discuss with you information about VMMC including its benefits, risks, relation to HIV, and what you need to do before and after receiving VMMC.

What is VMMC?

VMMC is the surgical removal of the foreskin of the penis. It is permanent (once performed, it cannot be reversed). VMMC reduces a man's chances of acquiring HIV by up to 60%. It indirectly reduces HIV infection in women once fewer men are infected by HIV. VMMC has other benefits, including improved hygiene, reduced penile cancer, reduced sexually transmitted infections, and reduced cervical cancer in female partners of circumcised men.

Why is VMMC necessary?

VMMC is recommended by the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO) as one of the methods for HIV prevention. At 60%, VMMC does not offer full protection against becoming infected with HIV, because a circumcised man can still become infected with HIV and can also infect others with HIV. Males from the ages of 10 years and above may receive VMMC if the health care provider determines that their health is suitable for the medical circumcision procedure. HIV-infected men may also receive VMMC, but becoming circumcised does not reverse HIV infection if a man already has HIV; however, it may offer some benefits to HIV-infected men such as improved hygiene, reduced genital ulcer disease (GUD). All eligible men seeking to get VMMC are encouraged to test for HIV, but this is not mandatory. It is recommended that all HIV-infected men, including those identified through VMMC services, be evaluated and enrolled for HIV care and treatment for their own health benefit and to prevent transmission of HIV to others.

What do I have to do after VMMC?

After surgical VMMC, you are advised to abstain from sexual intercourse for six weeks. You must return to the clinic on the 1st, 7th, and 42nd day after the procedure for review of your wound and to finally certify wound healing.

If you receive circumcision using a medical device you must return to the facility after seven days to remove the device, and you must abstain from sexual activity for six weeks after the device is removed. You should not remove the device by yourself, but instead you are to return to the VMMC provider for the removal and assessment of the wound and to get advice on wound care. You must return to the facility on the 14th and 42nd day for review and certification of wound healing.

You must rest for at least three days after VMMC (irrespective of method) to allow healing to take place normally. Strenuous exercise such as bicycle riding or lifting heavy weights may cause disruption to the VMMC wound, thus delaying wound healing or causing displacement of the device that may require surgical intervention.

You should avoid use of homemade potions, such as applying animal dung to the wound, since that may cause infections like tetanus. You should promptly return to the facility for follow-up at scheduled appointments, exercise sexual risk reduction including reducing the number of sexual partners, and use condoms upon resuming sexual activity.

What exactly is done? How long does it take?

Surgical VMMC: During surgical VMMC, the foreskin is removed by one of several methods including forceps-guided, dorsal slit, and/or sleeve resection. After counseling, you will be invited to enter the operating room (OR). The provider will explain the whole procedure in detail including the following steps: provider and assistant clean their hands and put on gowns and gloves; clean the penis and surrounding areas; give injection anesthesia; mark incision lines; cut along the marked lines; remove the foreskin; stop any bleeding; approximate skin edges; dress the wound and position the penis. This takes between 15 and 30 minutes. The injection comes with a little pain, but this quickly disappears as the medicine starts to work. Providers usually use local anesthesia, which means that they do not put you to sleep. As the provider starts to work, he or she will ensure that you are as comfortable as possible. The pain control from the anesthetic lasts at least one hour.

Device VMMC by PrePex: Once in the OR, the provider will explain the PrePex process in detail including the following steps: provider will clean hands and put on gloves; apply a local anesthetic [topical EMLA cream] to the site of the device placement (to remove pain at the site); assess the size of the penis; choose a PrePex device; place the inner ring; place the outer ring on the inner ring; assess the fit of the rings; position the penis; and give care instructions and discharge you. This takes between 7 and 15 minutes. You are advised to return to the clinic on the 7th day to remove the device and again on the 14th and 42nd day for follow-up.

Device VMMC by ShangRing: If you choose ShangRing and it is available at the site, the provider will explain the ShangRing procedure in detail including the following steps: provider will clean and glove hands; apply a local anesthetic [injection or topical EMLA cream] to the penis (to remove pain at site). In brief, the inner ring is placed around the penis at the coronal sulcus; the foreskin is held with four clamps and drawn over the inner ring; the outer ring is then positioned and clamped shut; and the foreskin is dissected with curved tissue scissors. The wound is cleaned with iodine and dressed with dry gauze. You are advised to keep the wound clean and dry, and to return to the clinic on the 7th day to remove the device and again on the 14th and 42nd day for follow-up.

The health provider will explain in detail the different methods and help you choose which options may be best for you. Not everyone is medically eligible for all options. Whichever procedure you choose, you will receive pain medication for up to three days. You will get additional instructions on how to take care of your circumcised penis.

Cost of VMMC

VMMC is offered to you for free. VMMC may be offered at a fee at other places such as private providers. In such places, the cost of VMMC will be discussed with the client before the VMMC is conducted. However, you will be responsible for the cost of your transport to and from the VMMC site.

Risks and Discomforts

VMMC may result in a few complications depending on the method used. For example some of these complications are as follows:

Surgical VMMC: Bleeding, pain, injury to the glans/shaft, swelling, discomfort (associated with sutures and sometimes dressings), or infection.

PrePex method: Swelling, smell, infection, post-placement pain, discomfort (associated with wearing the device), and displacement of the device.

ShangRing method: Placement failure, damage to foreskin, wound disruption, post-placement pain or discomfort (associated with wearing a device), infection, and displacement of the device.

To avoid and reduce these complications, the providers are well trained and careful during the entire procedure. They observe the highest level of clinical standards recommended by WHO, UNAIDS, and the Ministry of Health, including pain management and the use of appropriate medical equipment and supplies. To further reduce these undesirable effects, you are advised to follow the instructions given to you throughout the procedure and the written information sheet given to you at discharge. In case you have any complications, please inform us immediately using the contact information at the end of this document. You may need to go to the nearest health center or come back to this VMMC site if you have complications. Clients who experience placement failure or displacements of their devices before the 7th day may require surgical intervention to complete the VMMC. Fortunately, most sites can perform both surgical and device VMMC, so that there is available surgical back-up for managing any device failure of placement or displacements should these occur.

Benefits to Clients

VMMC is offered to you for free. It reduces your risk of becoming infected with HIV through sex with female partners. VMMC also confers other benefits to you: VMMC reduces some sexually transmitted infections (STIs), particularly ulcerative STIs, including chancroid, herpes, and syphilis, as well as balanitis, phimosis, and penile cancer. When many males in the population decide to become circumcised, the number of men with HIV decreases, and other people, including women, are less at risk for HIV infection. Female sex partners of circumcised men are also at less risk of cervical cancer. Note – that male circumcision does not offer 100% protection. It reduces (does not eliminate) the risk of HIV infection among sexually active HIV uninfected males.

Compensation for time and transport: VMMC is a health service; therefore, you will not be compensated for the time you spend at the site or for transport costs.

Confidentiality: Throughout the procedure, the facility ensures your privacy by restricting entry into clinical and operating rooms to staff only. All documents that have captured information about you are accessible by staff only during the provision of VMMC or follow-ups. After that, they are kept under lock and key with restricted access. This information may not be released without your written consent. However, this information is used routinely to

make progress reports about the VMMC service. Any other need to release information will follow applicable local government procedures and will not identify your name or address.

Voluntarism: Participating in VMMC is completely voluntary. Even if you decide now to have circumcision, you may change your mind before the procedure begins. Once the procedure begins, it cannot be reversed. The removal of your foreskin will be permanent. If you decide not to be circumcised, you will not be penalized or denied any other services by this facility or its health care providers. VMMC is also provided in other centers such as _____, _____, where you may receive it under similar conditions.

Contact information: If you have questions about VMMC, including questions about what we have discussed, you may ask me now.... [Pause for questions]

If you have questions later, please feel free to contact [name, contact phone or address including staff in the clinic and site manager]

Client Rights: The client's rights are displayed on the walls throughout the premises. If you have questions about your rights as a participant in VMMC, or wish to obtain further information, ask questions, or discuss any concerns about VMMC with someone other than the members of this team, please contact [details of who the client may contact such as MOH staff, or head of health services at district]

Consent

Consent/Assent: I _____
the undersigned, have received information about VMMC and understand the benefits and risks of VMMC. I give consent/assent to be circumcised at this site.

Signature: _____

[If unable to write, provider or witness may write name of client, capture thumbprint on signature line, and describe the owner of the thumbprint. This must be witnessed below.]

Consent: I _____ (parent/guardian) have received information regarding VMMC and understand the benefits and risks of VMMC. I consent for my child/relative/friend to be circumcised at this site.

Signature: _____

[If unable to write, provider or witness may write name of client, capture thumbprint on signature line, and describe the owner of the thumbprint.]

Staff (consent administrator or VMMC provider):

Name _____

Staff signature

Date

CASE STUDIES

[Case Study 12.1. Evaluation of the Informed Consent Process for Male Circumcision Scale-up in Zambia](#)

[Case Study 12.2. Improving Informed Consent Administration at VMMC Sites in Uganda](#)

TOOLS, INSTRUMENTS & GUIDANCE DOCUMENTS

The following documents, which are available online and in the accompanying external media (included with the hard copy version of this Guide), provide the background information or procedural guidance used for development of this chapter.

1. [UNAIDS Safe, Voluntary, Informed Male Circumcision and Comprehensive HIV Prevention Programming: Guidance for Decision-Makers on Human Rights, Ethical and Legal Considerations](#)
2. [Evaluation of the Informed Consent Process for Male Circumcision Scale-Up in Zambia](#)
3. [PEPFAR Technical Considerations for COP/ROP 2016](#)
4. [Sample Informed Consent Form](#)

ABBREVIATIONS

CQI	continuous quality improvement
EQA	external quality assessment
GUD	Genital Ulcer Disease
IC	informed consent
IP	implementing partner
MOH	ministry of health
OR	operating room
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
SIMS	site improvement and monitoring systems
STI	sexually transmitted infection
UNAIDS	Joint United Nations Programme on HIV/AIDS
VMMC	voluntary medical male circumcision
WHO	World Health Organization



CASE STUDY 12.1.

Evaluation of the Informed Consent Process for Male Circumcision Scale-up in Zambia

Between December 2009 and March 2010 the Population Council conducted an evaluation of the VMMC informed consent process with three main objectives:

1. Assess male clients' comprehension of key concepts in the informed consent process
2. Examine social norms and practices regarding informed consent for adolescents
3. Investigate how VMMC clients (adults and adolescents) who had recently undergone circumcision felt their experiences compared to their expectations.

The Population Council's findings (from 228 VMMC clients who participated in the comprehension assessment and 62 VMMC clients who participated in the semi-structured interviews) suggest that male circumcision clients comprehend most key concepts in the informed consent process. Areas that seemed to be understood best were the need to continue safer sex practices and aspects of wound care and healing. However, the concept of partial protection is not well understood: although many clients knew that MC reduces male's risk of HIV by 60 percent, few seem to recognize that they are at "lower" versus "low" risk of getting HIV. In addition, many clients believe that VMMC is partially protective against HIV, but fully protective against other STIs and cervical cancer in women, and there is a lack of awareness that VMMC does not protect female partners from HIV, except indirectly. In addition, benefits seemed to be better understood than risks.

Regarding informed consent among clients participating in semi-structured interviews, all adults and all except one adolescent had chosen to undergo MC voluntarily, with many emphasizing that it had been their own choice, free from pressure or coercion. Clients were less clear about the meaning of their signature on the informed consent form; some clients thought signing the form was freeing the service providers of all liability, whereas other clients did not recall signing a form providing consent. Interviews with clients, parents/guardians, and key informants indicated that consent procedures for minors are not well understood and are not being implemented consistently. In some cases, there is a lack of awareness about the age of consent (18 and older), and in other cases, parents have a strong influence regardless of the child's age.

The main recommendations by researchers included: (1) considering developing a discrete informed consent form for clients to sign that is separate from the other elements of the intake form; (2) or, if that is that form is infeasible, providing a laminated card that the provider could read together with the client before he signs to reinforce that he understands the risks and benefits and is agreeing voluntarily to undergo VMMC; (3) emphasizing risks and benefits equally in client information booklets; (4) reinforcing partial protection messages in settings with women; (5) making additional efforts to emphasize the lack of proven effect in reducing HIV risk among women and that protection against cervical cancer is only partial; and (6) acknowledging that most clients will experience some pain during or after VMMC surgery.

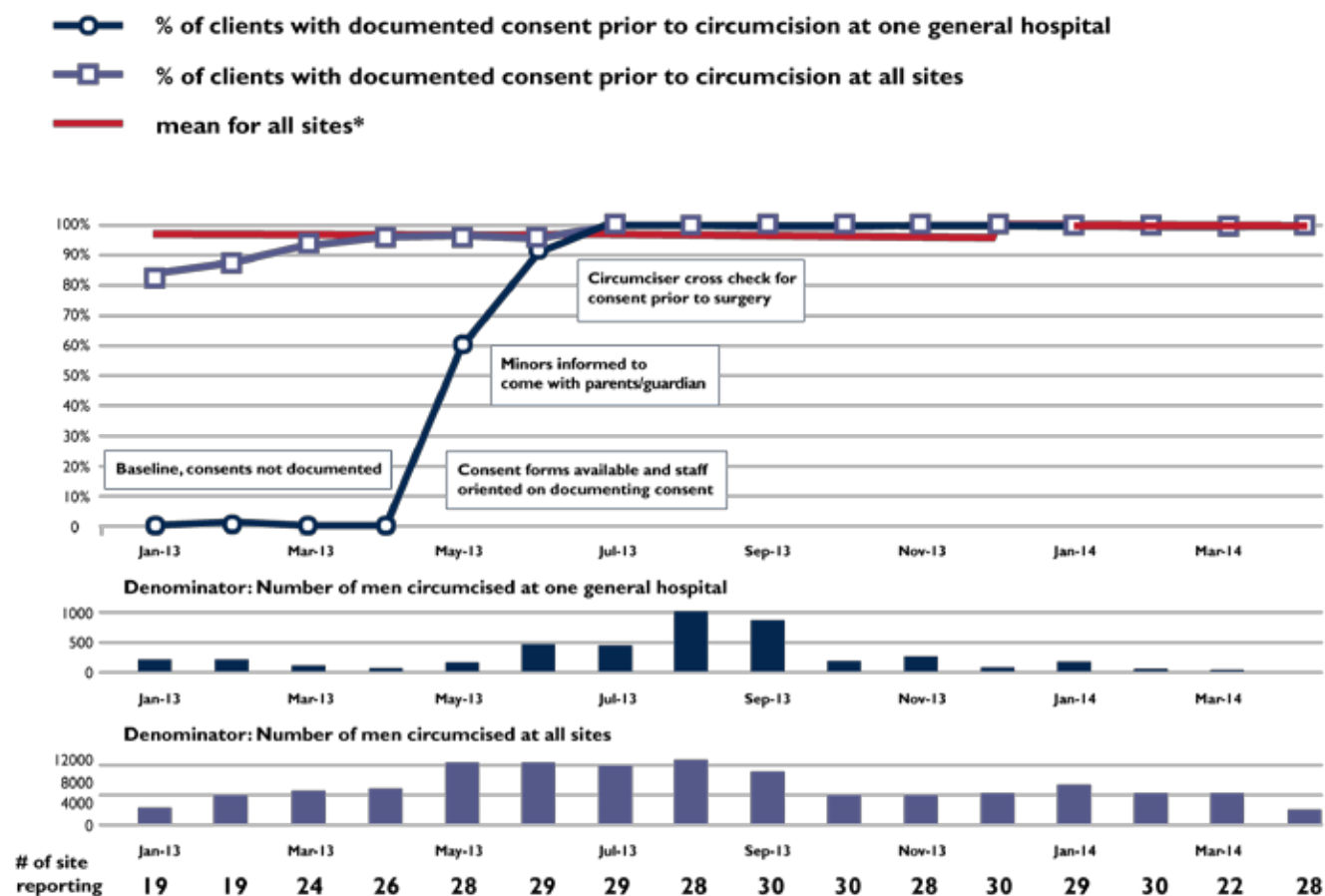


CASE STUDY 12.2.

Improving Informed Consent Administration at VMMC Sites in Uganda

In 2012 two PEPFAR-led external quality assessments (EQAs) found serious quality gaps, including lack of standardized registers, poor documentation of client informed consent, lack of emergency preparedness, and untrained providers. In response, USAID asked the ASSIST Project to support the Ministry of Health (MOH) and 10 implementing partners (IPs) to improve VMMC quality and safety in 30 sites using a continuous quality improvement (CQI) approach. ASSIST, MOH, and the IPs supported sites in forming improvement teams to identify barriers in achieving national standards, and to identify solutions (changes) to overcome the barriers and test these changes, while collecting performance data to measure whether gaps were bridged. A color-coded dashboard based on compliance with 53 standard categories was used by teams to measure progress. Figure 12.1 illustrates the dramatic change in informed consent administration from zero in March 2013 to 100 percent in July 2013 and maintenance of this high performance through the subsequent 12 months.

Figure 12.2.1. Percentage of Clients with Documented Informed Consent Prior to Circumcision





PEPFAR

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

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