



**PEPFAR**

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

## CHAPTER SEVEN.

MANAGING, MONITORING, AND REPORTING VMMC  
ADVERSE EVENTS

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

A Service Guide for Site Operations

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# CHAPTER 7.

## Managing, Monitoring, and Reporting VMMC Adverse Events

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### 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.

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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](#)].

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## 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](#)**

<b>Adverse Event Classifications and Definitions: During Surgery or Prior to Discharge from VMMC Clinic, or During Device Placement or Wearing</b>			
<b>ADVERSE EVENT</b>	<b>MILD</b>	<b>MODERATE</b>	<b>SEVERE</b>
<b>AN: ANESTHETIC-RELATED PROBLEM</b>			
<b>Surgery and Device</b>	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.
<b>BL: BLEEDING</b>			
<b>Surgery</b>	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 reexploration of the wound.	Intra-operative bleeding requiring blood transfusion, transfer to another facility, or hospitalization; or post-operative bleeding that requires surgical reexploration, hospitalization, or transfer to another facility.

ADVERSE EVENT	MILD	MODERATE	SEVERE
<b>Device</b>	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.
<b>PA: PAIN</b>			
<b>Surgery</b>	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.
<b>Device</b>	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).
<b>SD: SCARRING/DISFIGUREMENT/POOR COSMETIC RESULT; EXCESS SKIN REMOVAL; INJURY TO PENIS</b>			
<b>Surgery</b>	<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>
<b>Device</b>	<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
<b>BL: BLEEDING</b>			
<b>Surgery</b>	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 reexploration, hospitalization, or transfer to another facility; or any case where blood transfusion or intravenous fluid is necessary.
<b>Device</b>	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 reexploration, hospitalization, or transfer to another facility; or any case where blood transfusion or intravenous fluid is necessary.
<b>DD: DEVICE DISPLACEMENT</b>			
<b>Device</b>	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.
<b>IN: INFECTION</b>			
<b>Surgery and Device</b>	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.
<b>PA: PAIN</b>			
<b>Surgery</b>	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
<b>Device</b>	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**

<b>Scarring/ disfigure- ment/ poor cosmetic result; excess skin removal</b>	<i>Scarring</i> —Complaints by client in the absence of discernible abnormal scarring or disfigurement.	<i>Scarring</i> —Discernible but re-operation not required. Usually noticed first by the client and reported to the provider.	<i>Scarring</i> —Discernible and requires re-operation or referral/transfer to another facility.
	<i>Torsion of penis</i> —Torsion present but does not cause pain or discomfort.	<i>Torsion of penis</i> —Torsion present that causes mild pain or discomfort with erection but does not require surgery to correct.	<i>Torsion of penis</i> —Torsion present. Erections are painful and client cannot tolerate the appearance, discomfort, or pain. Surgery needed for correction.
<b>Surgery and Device</b>	<i>Insufficient skin removal</i> —Prepuce extends over the coronal margin but less than one third of the glans is covered in flaccid state.	<i>Insufficient skin removal</i> —Prepuce partially covers glans when flaccid but surgical correction is not necessary.	<i>Insufficient skin removal</i> —Prepuce covers most of the glans when flaccid and surgical correction is necessary.
<b>Injury to penis— Surgery</b>	<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.-



<b>ADVERSE EVENT</b>	<b>MILD</b>	<b>MODERATE</b>	<b>SEVERE</b>
<b>Injury to penis– Device</b>	<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.
<b>Excess skin removal– Surgery</b>	<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.
<b>Excess skin removal– Device</b>	<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**

<b>Surgery and Device</b>	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.
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#### **WD: WOUND DISRUPTION**

<b>Surgery</b>	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 reexploration or repair is required, or referral/transfer to another facility or hospitalization is required.
<b>Device</b>	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
<b>OA: OTHER ADVERSE EVENTS/EXCESS SWELLING OF PENIS OR SCROTUM, INCLUDING HEMATOMA; DIFFICULTY URINATING, OR OTHER</b>			
<b>Surgery and Device</b>	<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>
<b>Difficulty Urinating –Surgery</b>	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.
<b>Difficulty Urinating –Device</b>	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](#)].

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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).

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**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.
6. **Considerations for PEPFAR-Supported VMMC Programs Incorporating Tetanus Vaccination and Other Risk Mitigation Activities:** To be updated to reflect new WHO tetanus guidance.

## 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

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



# CASE STUDY 7.1.

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

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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 form 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.

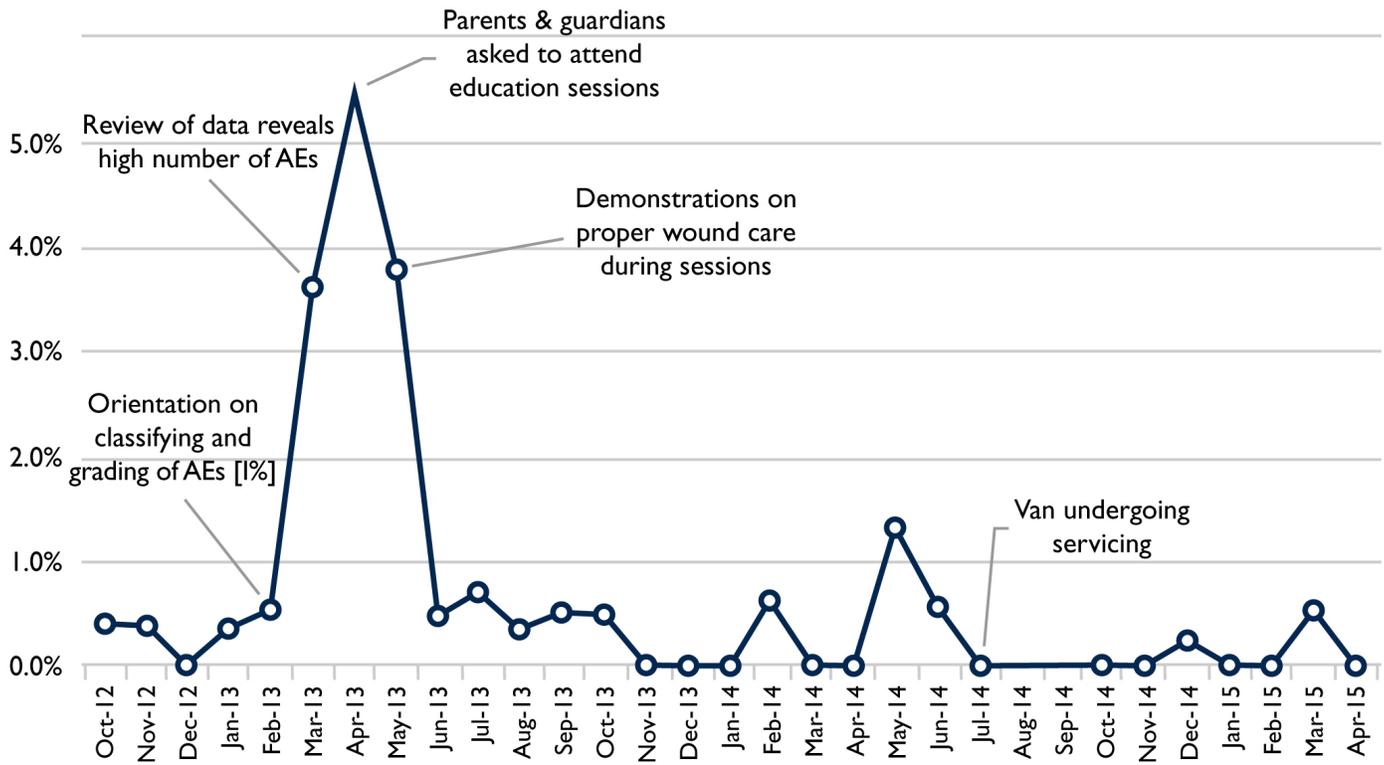
### IMPROVEMENT APPROACH

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

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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

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### 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:

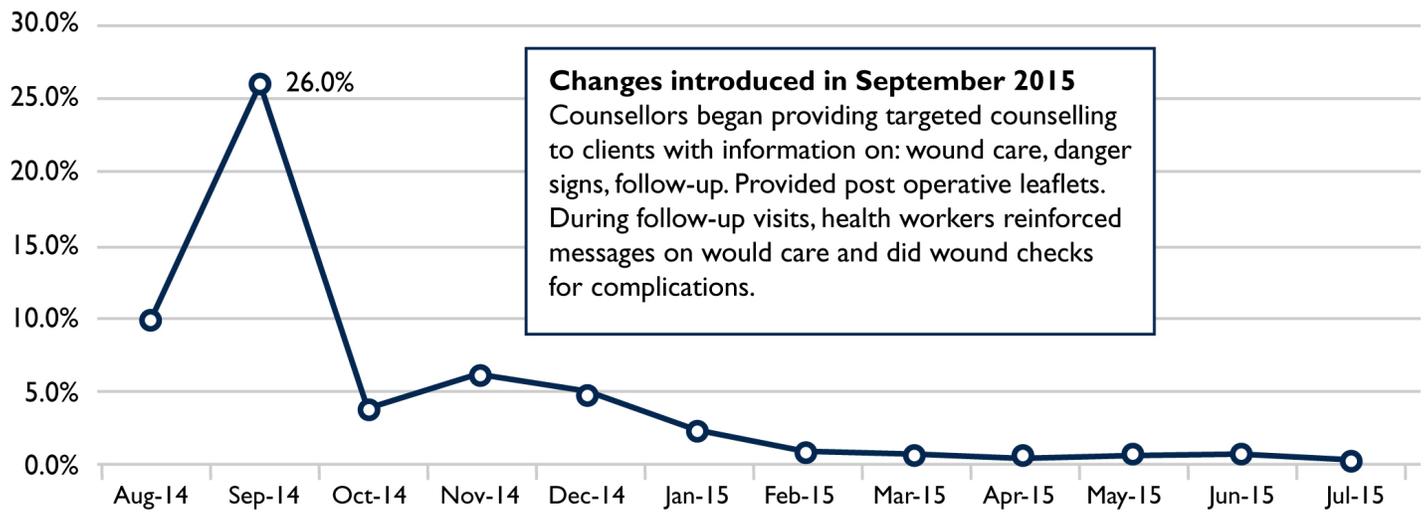
- Reviewing baseline findings to define and find root causes of gaps
- Training, coaching and mentoring staff at the site on preventing, identifying, managing, reporting, and tracking adverse events
- Introducing missing tools, revising existing tools, and working with the team on using tools, including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

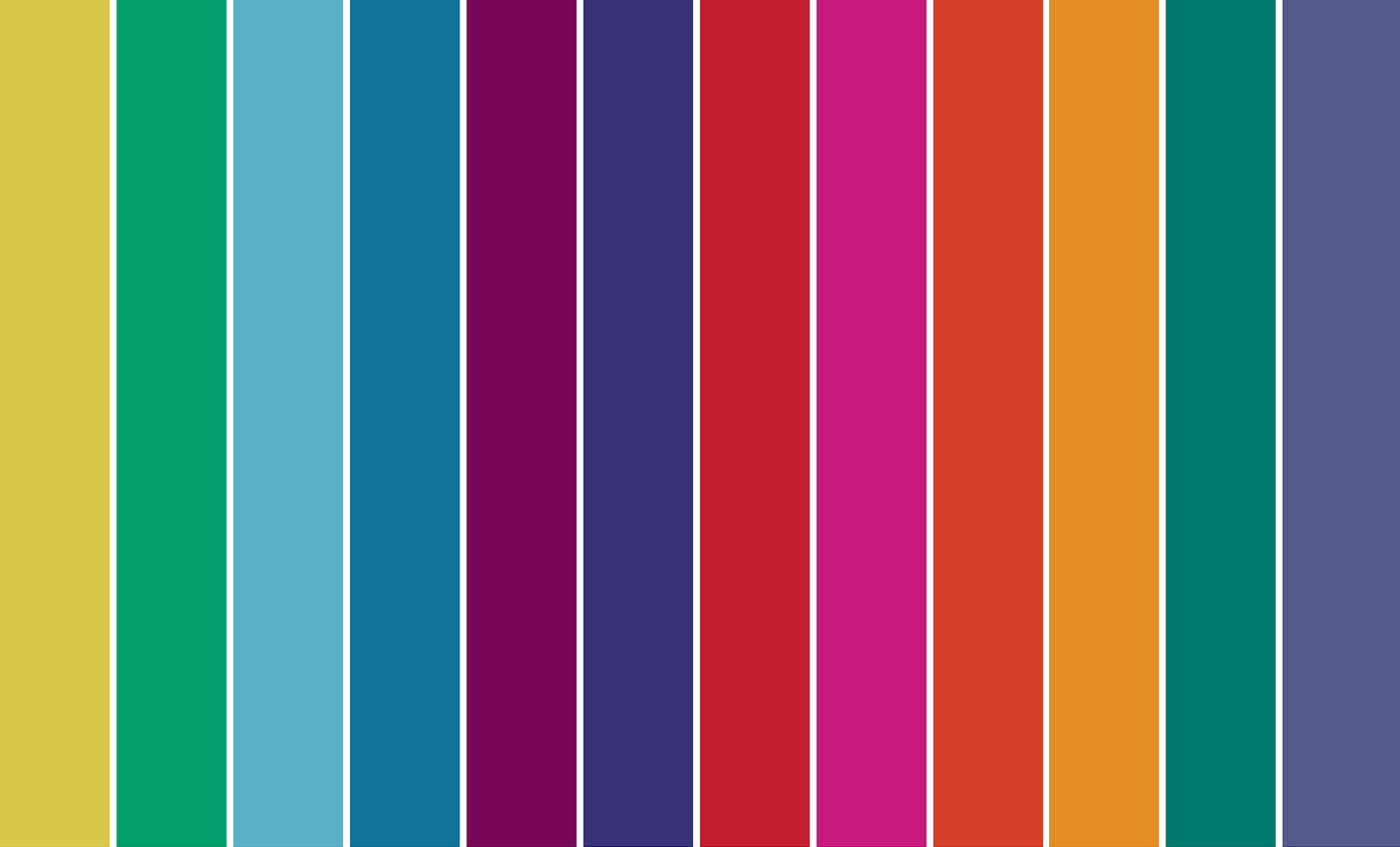
The VMMC CQI team further reorganized counseling sessions. They introduced counselors on a rotational basis to provide information on: 1) wound care before and after surgery, including avoiding application of homemade portions such as cow dung on the wound; 2) danger signs and facility contacts to call 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**





# PEPFAR

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

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