

10. Adverse Event Management, Monitoring, and Reporting

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

Objective(s):

- To manage clinical adverse events related to VMMC surgery
- To ensure appropriate referrals for adverse events

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

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

General AE management for VMMC programs (see GUIDANCE DOCUMENT 8):

- Equipped Sites and Trained Staff
 - Sites must be equipped to handle life-threatening emergencies, and trained staff should always be available while VMMCs are taking place.

- Client Education
 - Clients must be given sufficient education on the risks of VMMC surgery. Although AEs are rare, they are still possible—even in sterile environments with experienced staff. Clients need to be educated about the proper techniques for post-surgical care (e.g., washing practices, keeping the bandage and wound site clean, removing the bandage). Site staff must remind the client of the importance of adhering to post-operative follow-up recommendations. These recommendations state that all clients, regardless of their healing status, should return to a clinical site within seven days following surgery. Clients must also be reminded that sexual abstinence is required for six weeks after VMMC. Clients must be informed of signs of complications and what should be done to manage them correctly. It is imperative that all clients know where emergency care can be found. All clients must also be provided with phone numbers they can call for emergency services, if complications arise.
- Post-operative Monitoring
 - It is important to observe and follow clinical signs (vital signs) of each client for at least 30 minutes after the VMMC, because this is the period when post-operative AEs most commonly become apparent.
- Follow-up Visits
 - Routine follow-up should occur within seven days of the initial VMMC to assess any AEs. Treatment of any mild AEs can happen during the follow-up appointments, or if necessary, during the appropriate referral.
- AE Rate Calculations
 - It is important to monitor and calculate the AE rates accurately in each service delivery site as well as monitor program-wide rates to ensure that they are not above expected AE rates. AE rates can be calculated by the number of clients with an AE(s)/total number of clients who return for follow-up. If a client does not return to a facility for follow-up care, then that client will not be counted in the AE rate denominator.

Adverse Event Monitoring and Management

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