

Update Log: Adverse Event Action Guide for VMMC by Surgery or Device, 2nd Edition, 2016

Date	Section	Changes
2016	Initial release, 2 nd edition	N/A
August 2017	Injury to Penis	Revised and expanded beginning text to provide more guidance on prevention of injuries, and management of fistulas, based on interval experience.
August 2017	Excessive Bleeding	Edited bleeding management algorithms to clarify scope and intended audience of each. Expanded management guidance on moderate intra-operative and post-operative bleeding to include specific instructions for holding pressure. Expanded management guidance for severe intra-operative and post-operative guidance to include addressing frenular artery bleeding, avoiding wound re-exploration in suspected bleeding disorders, and advanced management in suspected bleeding disorders.
August 2017	Pain	Minor additions on additional clues to infection and specifically necrotizing fasciitis
August 2017	Wound disruption	Added cautions about closing disrupted wounds open >48 hours, noting that it is often better to allow them to heal by secondary intention
August 2017	Scarring and disfigurement	Added description of subcutaneous nodules as preventable AEs in this category.
August 2017	Injury to the Penis	Major section reorganization, adding specifics on types of injuries and expanding guidance on fistula prevention based on additional experience, and on the necessity to refer fistulas for specialist management to avoid causing further damage by attempted repair. Also added guidance on avoiding diathermy in cases of glans amputation as this interferes with reattachment.
August 2017	Problems with voiding	Added urethral stricture due to urethral damage as a cause.
August 2017	Emergency Management	Added preservatives in anesthetic vials as a potential cause of anaphylaxis. Added guidance on the necessity of transferring clients with anaphylaxis to facilities with intensive care capabilities to due potential for late relapse.
August 2017	Multiple sections	Minor wording clarifications
March 2018	Multiple sections	Added links to Project IQ resources at the end of relevant sections. Updated Bleeding section and bleeding algorithms in Appendix to reflect availability of ancillary treatments such as tranexamic acid, fibrin glue, and others; and to define "significant blood loss" for non-VMMC providers.
November 2018	Injury to Penis	Clarified language throughout section; added special instructions for glans injury management, including tissue handling, referral, and repair; added job-aid for managing glans injuries (in Appendix); made more prominent that diathermy should not be used in the frenular area. Added language about catheterization after injury to penis.
December 2020	Adverse Event Timing	Clarified language for surgical circumcisions, changed timing classification for devices from A1/A2/B/C to A/B/C/D, and

		edited definitions of device timing periods to simplify and better align with clinical events. Device AE timing classification updated throughout all sections of guide including minor wording clarifications as needed.
December 2020	Device Displacement	Major revision of device displacement section including definition and severity. There is now a mild category and moderate/severe device displacements added to the list of notifiable AEs for PEPFAR-supported programs. Edits extended to all sections where device displacements are referenced.
December 2020	Multiple sections	All specific references to the PrePex elastic collar compression device removed (except for historical reference in the tetanus section) since this device no longer in use.