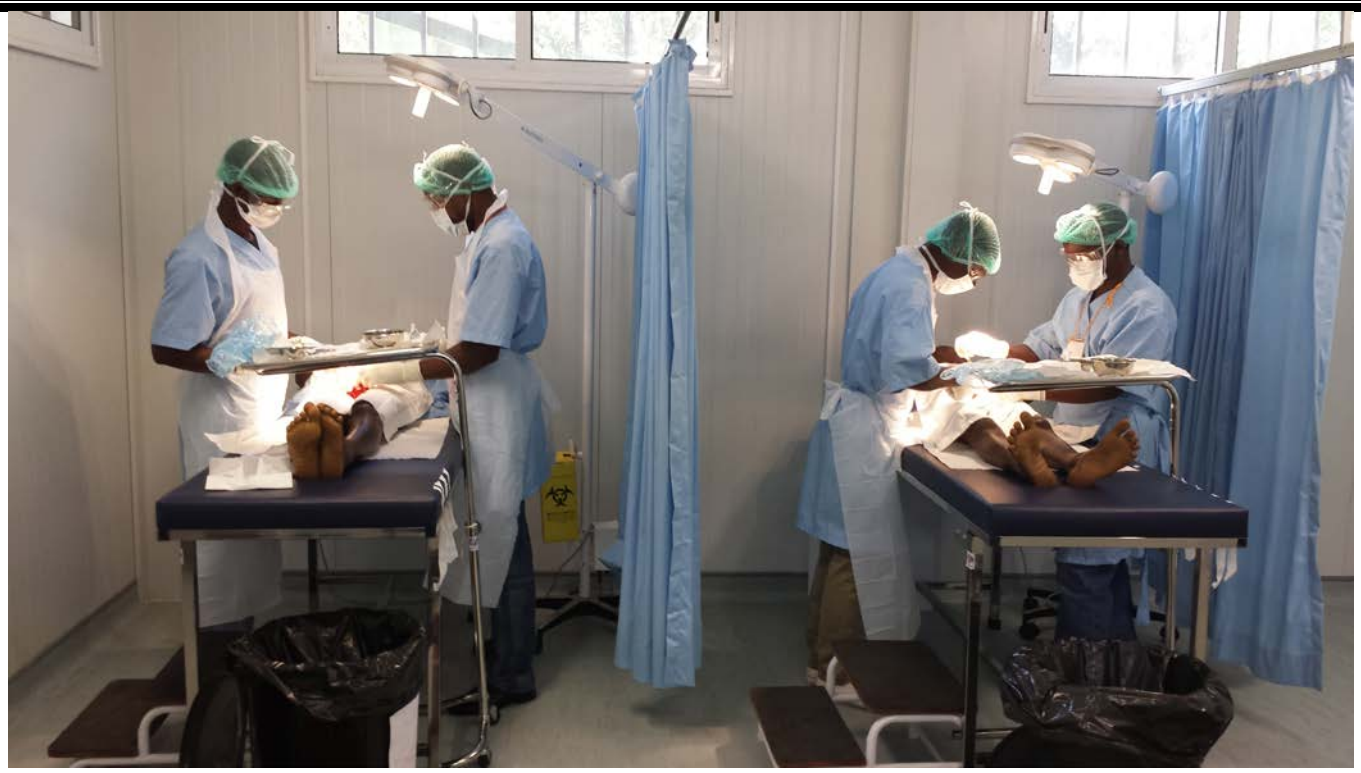
Adverse Event Action Guide

For Voluntary Medical Male Circumcision (VMMC) by Surgery or Device

2nd Edition, 2016



ACKNOWLEDGMENTS

This guide is the result of collaborative work between Population Services International (PSI) and the College of Surgeons of East, Central and Southern Africa (COSECSA) together with contributions from numerous clinical and public health experts. The U.S. Centers for Disease Control and Prevention (CDC) provided technical input throughout the development of this document. The following people contributed to the writing and production of the guide:

- Dr. Renee Ridzon (consultant to CDC)
- Dr. Stephanie Davis (Medical Epidemiologist, CDC)
- Dr. Dino Rech (Co-CEO, Centre for HIV and AIDS Prevention Studies [CHAPS])
- Mr. Christopher Samkange (Director, Continuing Health Education, University of Zimbabwe, COSECSA-ASEA)
- Dr. Karin Hatzold (Global Deputy Director HIV Clinical and Biomedical Interventions, PSI)
- Dr. Jonas Hines (Medical Epidemiologist, CDC)

The authors would like to acknowledge the contribution of:

Professor Milliard Derbew, President, College of Surgeons of East, Central and Southern Africa (COSECSA) and Chair of Paediatric Surgery Addis Ababa University; Professor Mohammed Labib, COSECSA and Professor of Urology, Namibia Medical School; Petra Stankard, Senior Technical Advisor HIV/TB, PSI; Jonathan Grund, Health Scientist, CDC; for their invaluable feedback and timely reviews; the clinical staff from Society for Family Health (SFH), CHAPS South Africa, PSI/Swaziland, PSI/Zimbabwe, and SFH/Zambia for their willingness to field test this guide and provide feedback.

Special thanks go to the participants at the World Health Organization (WHO) Expert Consultation on the Male Circumcision Adverse Event Action Guide for their contributions to this document:

Julia Samuelson, WHO; Timothy Farley, WHO/ Sigma3 Services; Elijah Odoyo-June, CDC; Timothy Hargreave, Consultant; Naomi Bock, CDC

ONLINE ACCESS

An electronic version of this guide is available on the Clearinghouse on Male Circumcision for HIV Prevention: http://www.malecircumcision.org

Table of Contents

SECTION 1-INTRODUCTION TO THE ADVERSE EVENT ACTION GUIDE

PURPOSE

The purpose of this Adverse Event (AE) Action Guide is to:

- Reduce the incidence of AEs in medical male circumcision (MC) by providing guidance on how to avoid them
- Improve the outcomes of AEs associated with both surgical and device-related MC, by providing guidance on safe and appropriate management
- Facilitate standardized reporting of AEs
- Support monitoring of the quality of programmes and safety of voluntary medical male circumcision (VMMC) programme services

AUDIENCE

This guide is appropriate for any programme implementing MC under local anaesthesia in adolescent and adult males as part of a comprehensive HIV prevention strategy. Although this guide has been prepared for programmes supported by the US President's Emergency Plan for AIDS Relief (PEPFAR), it is hoped that it will be useful to providers in all VMMC programmes, as well as those who conduct post-operative reviews of clients but may not be trained to provide the MC procedures themselves.

UPDATES IN THE SECOND EDITION

This document has been updated from the initial version, primarily to include definitions and management of AEs associated with WHO-prequalified MC devices, as well as to provide other updates based on additional VMMC implementation experience, including AE reporting to WHO and to PEPFAR through the Notifiable Adverse Event reporting system. These updates include:

- Definitions for PrePex and ShangRing device-related AEs, the only two WHO prequalified devices at the time of writing, including an additional device-specific AE: Device Displacement
- Timing scheme for device-related AEs
- Infection chapter expanded to include tetanus and serious necrotising infection
- Reference to WHO recommendations regarding the risk of tetanus with use of the PrePex device
- Additional guidance on the prevention and management of bleeding and additional discussion on bleeding disorders
- Additional guidance on infection control through safe injection techniques and avoidance of contamination through use of multi-dose vials
- Renaming of AE "Sexual difficulties or complications/undesirable sensory changes" to "Sexual difficulties or effects/undesirable sensory changes"

- Local anaesthetic dosing charts simplified and modified to include suggested starting doses; volumes of both starting and maximum doses are limited based on syringe size
- Bupivacaine can be used with lidocaine in VMMC clients of all ages
- Additional detail on policies and responsibilities for reporting AEs
- Inclusion of references to pertinent updated guidelines (such as for post-exposure prophylaxis) and other documents
- Additional material added including an AE definition chart, algorithms for management of bleeding and haematomas, AE timing chart, anaesthetic dosing charts, and recommended emergency management supplies
- Charts within the text of the guide and as appendices that can be used to produce full colour job aids
- Addition of colour-coding to the AE charts, with yellow, pink, and orange denoting surgery, devices, and surgery and devices, respectively

ORGANIZATION OF THIS GUIDE

Reading the entire guide will result in the best understanding of classification, management and reporting of AEs. Throughout this guide, the phrase ‘male circumcision’ or ‘MC’ is used to denote the procedure of removal of the foreskin, and the phrase ‘voluntary medical male circumcision’ or ‘VMMC’ refers to the programme providing circumcision services for HIV prevention.

Section 1 is this introduction.

Section 2 gives key background information about AEs, including criteria for classifying severity (mild, moderate or severe) and timing of AEs for both surgery and device circumcisions; an overview of the process of AE identification, management and reporting; and PEPFAR-specific reporting requirements.

Section 3 gives detailed diagnosis and management information for **each specific AE type.** It will likely be of most interest to providers who manage AEs, and they should familiarize themselves with these definitions and management principles prior to providing care to VMMC clients. Each AE type has a separate chapter, which begins with general information and considerations for that AE type, including a section on “additional and special considerations for devices”. This is followed by charts providing definitions and specific management for first surgical and then device methods. In some cases these are identical, and in others they differ.

Section 4 consists of appendices that can be used as job aids, including a guide to abbreviated AE coding, condensed charts listing diagnostic criteria for all AE types, a list of recommended emergency supplies for sites performing MC, flow charts for management of bleeding or haematomas, and anaesthetic dosing charts.

SECTION 2-ADVERSE EVENT DEFINITION, CLASSIFICATION AND REPORTING

General definition for AEs related to MC: ***Any injury, harm or undesired outcome that occurred during or following the male circumcision procedure that would not have occurred if the client had not undergone the procedure. This includes not only events related to any error in screening, performance, or follow-up of the procedure, but those in which no error occurred.***

AEs are inevitable with an intervention such as MC, and occurrence of an AE does not automatically imply provider error or fault. Nonetheless, much can be done to reduce the risk and severity of AEs, including:

- use of proper supplies
- use of instruments that are in good working order
- correct cleaning and sterilization of instruments
- proper training of providers and retraining as needed
- emergency supplies on site with periodic emergency training
- early recognition of and follow up of clients with AEs
- correct management of AEs
- documentation of AEs
- evaluation of AE data and institution of changes and corrections to programmes and policies as indicated
- policies empowering all staff to alert an appropriate above-site party of practices that could lead to AEs (such as use of the forceps-guided circumcision technique in adolescents under 15 years), without fear of untoward ramifications

ADVERSE EVENT DEFINITIONS

AE definitions used in this guide are based on those in the PEPFAR Monitoring, Evaluation and Reporting (MER) Indicator Guidance. Because the majority of VMMC programmes are PEPFAR-funded, discussions of reporting in this guide also include PEPFAR reporting requirements. Other definitions have been in used in some settings, and some ministries of health may require providers to use different definitions in reporting.

AE classification has three common components: **type, severity, and timing**. Severity and timing are defined here, and types are explained in detail in the management section. **AE relatedness to MC** is a fourth component that is primarily important in AE investigation and monitoring, and discussed on p.11.

In most cases, classification and definitions for surgical and device-related AEs are the same or quite similar. However, in some cases there are differences due to technique and mechanisms of action.

ADVERSE EVENT SEVERITY

AEs have been classified into three categories of severity: mild, moderate, and severe.

- **Mild** classification indicates minimal or no intervention is required beyond reassurance and observation
- **Moderate** classification relates to those AEs that are neither mild nor severe, require intervention, and are usually managed on-site
- **Severe** classification requires extensive intervention with referral or specialist input

Moderate and severe AEs are those that in the past PEPFAR has required be reported and monitored. AEs are no longer a required reporting indicator for PEPFAR MER, but moderate and severe AEs should still be the AEs of greatest interest to national reporting systems.

As VMMC programs expand into more remote areas where health care facilities have limited capacity, increasing numbers of males are presenting with AEs to facilities that are unable to provide care for mild and moderate AEs. Transfers necessitated by this situation should not automatically result in a "severe" classification: severity should instead be determined based on clinical characteristics of the AE and level of intervention required as recommended in this guide. Similarly, hospital admissions necessitated only by distance or social considerations rather than the level of care needed should not result in an automatic 'severe' classification.

This recommendation applies to device-based MCs as well: if a client presenting with an otherwise moderate AE is transferred because the site to which he presented cannot provide appropriate care (e.g. suture materials are not stocked or staff are not trained in suturing), the transfer itself does not constitute a severe AE criterion. Surgical intervention for device AEs, including circumcision, remains a criterion for severe AE.

ADVERSE EVENT TIMING

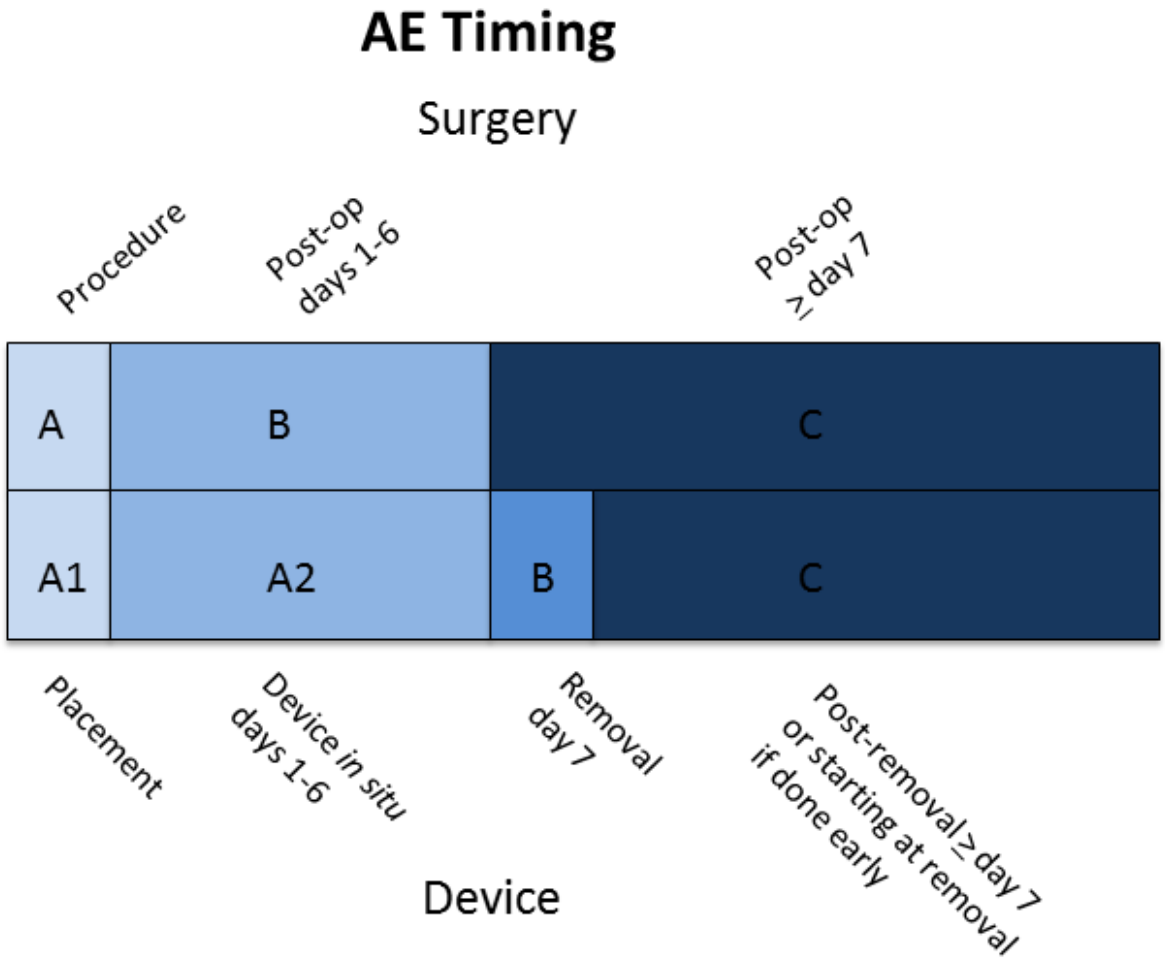
For MCs performed **surgically**, AEs are classified by their timing in relation to surgery as follows:

- A = intra-operative (AE occurs during surgery or prior to discharge from clinic)
- B = post-operative (AE occurs 1–6 days after surgery and discharge from clinic)
- C = post-operative (AE occurs ≥7 days after surgery and discharge from clinic)

For MCs performed **using devices that remain *in situ***, AEs are classified as follows:

- A1 = during placement of PrePex or ShangRing device
- A2 = after device placement and before removal (these AEs typically occur 1-6 days post-placement)
- B = during device removal
- C = after device removal (typically after day 7)

- If a device is displaced or removed early:
  - This should be classified as Device Displacement in the A2 period.
  - However, complications or AEs after removal of the device should be classified as C, even though the device was removed early.



This chart and a list of AE definitions are included as Appendices 2, 3 and 4.

In the diagnosis and management charts in this guide, device AEs occurring in time period A1 are addressed in the intra-operative charts, and

those occurring in periods A2, B, and C are addressed in the post-operative charts. For example, pain that occurs during device removal (B) is found in the post-operative, not intra-operative, chart.

AE timing is classified by when the first AE occurs. For example, if a client presents 8 days after surgery with an AE but gives a history of onset at day 6, timing would be classified as B, not C. The exception is injury to the penis, where the AE should be classified by when it was noted, since management can depend on how much time has passed since circumcision.

By the nature of their natural history, not all AEs can occur at all time-points. For example, scarring can only be classified as C since it cannot occur at the time of the procedure and cannot be identified in the first week after surgery, since seven days is insufficient time for scar formation.

AEs sometimes occur together and can be related (for example, wound disruption may result from wound infection). Each AE noted should be recorded as a separate diagnosis (wound infection with disruption would be recorded as 2 AEs), and the presence of one AE may affect treatment for another (e.g., wound disruption should not be closed while untreated infection is present).

With many AEs, **documentation by photographs** is very helpful in classification and monitoring progress and treatment. When photographs are obtained, client/guardian permission should or must be obtained, depending on the policy or preferences of national programmes. Permission may be written or verbal, also depending on policy or preferences of national programmes. In this guide, chapters on specific AEs indicate where repeated photographs may be particularly helpful.

ADVERSE EVENT RELATEDNESS

AEs can also be categorized with regard to relatedness to the procedure. This is most often done during an investigation process for a serious AE, rather than in routine diagnosis of common AEs. During this process, the assessed degree of relatedness to the procedure may change as new information is obtained. Relatedness does not impact management of an AE.

An AE is considered related to the procedure **if it would not have happened had the procedure not been performed**. **This does not necessarily imply any error or wrongdoing on the part of the provider.** For example, infection of the circumcision wound as a result of applying a traditional remedy, or displacement of a device due to sexual activity, are considered definitely related to the procedure, even though the clients did not follow instructions, as neither would have occurred had there not been MC. Neither, however, occurred because of provider error.

Regardless of being determined to be related to MC or not, all AEs should be recorded and reported, even when the AE seems to be completely unrelated (e.g., client involved in a road traffic accident 3 days after operation).

Relatedness can be classified as:

- ***Definitely related*:** Direct association with the procedure, i.e., follows a reasonable temporal sequence from the procedure and is a recognized AE of the procedure.
- ***Likely/Possibly related:*** More likely explained by the procedure, i.e., follows a reasonable temporal sequence from the procedure and is a plausible AE of the procedure, but could have another cause.
- ***Likely unrelated:*** More likely explained by other cause.
- ***Definitely unrelated:*** Clearly explained by other cause.

OVERVIEW OF ADVERSE EVENT IDENTIFICATION, MANAGEMENT AND REPORTING

In general, identification and management of an AE follows the time course depicted below.

1. **Identification: The AE may be revealed by the client or discovered by the provider during surgery, during the post-operative observation period, or at a subsequent visit.** The health care worker providing care should first identify and classify the AE. As many people own cell phones with the capability of taking and sending photographs, providers may find it helpful to have clients send photos when they call with complaints or with reports of progress. While cell phone communication and photos about healing during the post-operative period are acceptable and can be used for monitoring, all initial AE identification and treatment must be conducted through direct observation by a clinician. A list of the various types of MC-related AEs, as well as definitions of the respective severity levels, can be found in Section 2.
2. **Treatment:** Once the AE is identified and classified, the provider is encouraged to follow the treatment guidelines in this document. **The management of AEs described in this guide constitutes the basic standard of care. Where there are national protocols with enhanced standards of care, these should be used**.
    a. Please note that the medications mentioned in this guide, specifically antibiotics, are given as examples. Local availability, drug resistance patterns, and national treatment protocols may vary. Thus, national programmes should adapt this guidance accordingly.
    b. In most cases, management of surgical and device-related AEs is the same or similar. However, with device-related AEs, management may also include early removal of the device and/or performance of a surgical circumcision, based on clinical judgement.
3. **Referral, if necessary:** Referral to another health facility or provider (e.g., specialist doctor) may be necessary**.** Providers are advised to refer clients or request help with every AE that they do not feel comfortable with or capable of managing according to the treatment guidelines provided, even if the site of care is in theory equipped to handle the AE. Even when admission to a higher level of care is not called for in the management of the AE *per se,* consideration should be given to the travel conditions and distance required for return visits to the local site; sometimes transfer and admission may be needed to assure client safety and follow-up, even if not strictly medically required. Ensuring successful referrals depends on adequate planning beforehand. VMMC service delivery points should have a readily-available, up-to-date contact list of sites and appropriate specialists to which referrals can be made at any time the need arises. This list should be checked every six months to make sure that it is up to date. These providers and sites should be aware of the possibility of MC clients being referred for assistance.

4. **Reporting**: Proper reporting is important so that providers can follow-up with the client as necessary, and managers and providers can monitor the quality and safety of a programme and take actions to improve client care. Reporting should follow nationally prescribed reporting pathways and protocols. Providers and other clinic staff need to understand and follow these protocols. Site and programme managers must understand how and when to report AEs and when to inform external stakeholders. PEPFAR-funded programmes are no longer required to report all moderate and severe AEs to PEPFAR, but are still required to follow the PEPFAR Reporting Protocol for MC Client Death and Notifiable Events (see next section), and should follow any additional reporting guidance provided by national programmes and by their funding agency's in-country VMMC staff.
5. **Follow-up:** Routine follow-up ensures that clients receive sufficient care after circumcision. Providers and site managers should ensure that clients are well-informed about the importance of routine follow-up visits and when they are expected, as well as the importance of specific and additional follow-up visits when an AE has occurred. Clients with a documented AE who default on follow-up appointments should be contacted by telephone or any other appropriate means. An enquiry should be made as to their current status as well as actively encouraging them to present for follow-up review.

REPORTING AND MONITORING ADVERSE EVENTS

Reporting AEs involves passing summary information about AE rates and/or notifiable individual AEs up through designated channels to programme and/or ministry of health leadership. Monitoring can be done at any level and involves reviewing and analysing these data for trends and concerning findings.

ADVERSE EVENT REPORTING

Reports of AEs provide data necessary to conduct monitoring of service delivery, safety, programme progress and patient outcomes. AEs should be reported according to national ministry of health guidelines if present, and regardless, programmes should continue internal AE reporting for quality control. Reporting systems should include clear guidance on:

- *The severity threshold for AE reporting.* Historically, PEPFAR programmes have been required to report all moderate and severe AEs. This routine reporting is no longer required. However, "moderate and severe" can still be a useful threshold for reporting.
- *Standard AE definitions to be used*, such as the standard definitions provided in this guide. This document recommends the use of AE definitions originally provided by PEPFAR for AE reporting, but some ministries of health may require programmes to report using different AE definitions.
- *Reporting methods and timing*.
- *The expectation that AE's should be reported regardless of the appearance of relatedness*; follow-up investigations as needed will make the final determination of relatedness.

There is a subset of severe AEs for which reporting is also expected to external stakeholders such as donors, WHO, or technical advisory groups. WHO requests reporting on serious AEs, including deaths; hospital admissions to intensive care within 30 days of an MC; tetanus cases within 30 days of an MC; and serious glans, penile or urethral injuries. National Ministry of Health reporting structures should include this step at some level.

Similarly, programmes for which PEPFAR provides direct service delivery support are still required to rapidly report specific notifiable AEs through a separate PEPFAR process, under the **PEPFAR Protocol for VMMC Client Death and Notifiable Adverse Events**. The most recent version of this protocol should be followed, under the direction of the in-country VMMC staff of the funding agency. The protocol includes information on processes to ensure that appropriate parties at the country and headquarters levels are rapidly notified of any client deaths or notifiable AE, including:

- complete or partial amputation of the glans or shaft of the penis
- tetanus, including non-fatal cases
- any AE that results in disability that is likely permanent
- any AE that results in anatomic deformity that is likely permanent
- any AE that results in hospital admission for ≥3 days

This protocol applies to any death or notifiable AE(s) that occurs during the MC procedure or within 30 days following surgical circumcision or device removal, for any male, regardless of age, who was circumcised through services or research directly funded by PEPFAR. If there is any evidence that a death or notifiable AE occurring after the 30-day post-MC mandatory reporting period is related to the MC, this should also be reported. The list of reportable AE types may change in the future, and providers at PEPFAR-supported sites should be aware of the up-to-date requirement for AEs that need to be rapidly reported.

This reporting requirement does **not** apply for programmes receiving only technical assistance from PEPFAR. However, programmes and ministries of health are encouraged to require that all deaths and notifiable AEs be reported to them regardless of funding source, to enable more complete reporting from all service delivery points.

Admissions to a hospital for ≥3 days to provide care for mild and moderate AEs that are necessitated by the non-medical circumstances of the client, such as limited capacity at health care facilities near clients' home and far distances between clients' homes and health care facilities, should **not** be reported as a notifiable AE.

Implementing organizations and ministries of health should have processes in place by which providers and other staff can alert the organization (at above-site level), the funding agency, and/or the ministry of health to improper conduct that has led or could lead to AEs, such as use of forceps-guided technique in those under 15 years of age. These processes and accompanying policies should ensure there are no untoward ramifications for submitting such alerts. Field staff should be urged to use these processes whenever unsafe practices are observed.

ADVERSE EVENT MONITORING AND INVESTIGATION

Regular monitoring of reported AE data provides the necessary insight for quality assurance and improvement. All programmes should monitor the number of VMMC clients experiencing AEs as a way of measuring safety and the quality of service provision. Reports are used to calculate AE rates and, as with definitions and reporting methods, calculations of AE rates should be done using defined formulae. One such formula is:

Number of clients with at least one AE in a given time period / Number of clients with at least one post-MC follow-up visit in the same period

An AE rate above 'an acceptable level' (often considered 2% for moderate and severe AEs combined) is an indication of the need for investigation into causes of AEs and possible corrective interventions. Conversely, extremely low AE rates (near 0%) may suggest problems in the monitoring and reporting systems, such as poor follow-up rates, failure to recognize AEs, or incorrect classification of AEs. Monitoring should be conducted at multiple levels (e.g., site, region, implementing partner), so that comparisons can be made. Such comparisons allow recognition of possible problems with specific sites, regions, implementing partners, or an entire national programme, so that any needed improvements can be made at the appropriate level.

For PEPFAR-supported programmes, PEPFAR participates in investigation of reported notifiable AEs. For all programmes, it is recommended that ministries of health and/or programmes direct such investigations for all instances of severe AEs, AE clusters or high AE rates. These should include classifying AEs by relatedness to MC.

DETERMINING REPORTING RESPONSIBILITIES

In cases where multiple providers or sites are involved in a client's care, confusion can arise over who is responsible for reporting AEs. Examples would be: a client with an AE presents to the site where the procedure was performed, but requires referral to another site for management of the AE, and because of concerns about duplicate reporting, neither site reports the AE; or, a client with an AE presents to a different site from where the MC was performed, and this site is concerned about inflating its own AE rate by reporting the AE. It is important to have a single, clear policy that governs reporting responsibility. Below is an example of a possible policy. Programmes may choose to adopt some or all of the elements of the example in their policies. Regardless of the details of the policy, national programmes and implementing partners need to collaborate to develop policies for reporting of AEs that:

- ensure that all reportable AEs are reported to the national programme
- define proper reporting channels and responsibilities for reporting
- avoid duplicate reporting
- provide education on proper management, referral and reporting of AEs to all sites where men with MC-related AEs may present

Example of a policy for reporting MC-related AEs:

- When one provider performs a MC and another provider at the same site diagnoses an AE, the provider diagnosing the AE should document it and ensure it will be reported.
- When an AE is diagnosed at the site where the MC was performed, that site should report the AE, regardless of whether the client is then transferred elsewhere for care.
- When an AE is diagnosed at a site that did not perform the MC (and possibly does not perform MCs at all), as may be common in the case of campaigns or mobile services, the site that performed the MC should be notified, and it should document and report the AE. To ensure this is implemented correctly, VMMC sites should educate health posts and clinics in their catchment areas about the need to contact the MC provider in the event that a recently circumcised client presents with an AE.
- This policy requires that sites performing MCs have a standard procedure for ensuring that when one of their MC clients is diagnosed with an AE at another site and they are notified, the MC site staff reliably document the AE in the client's MC chart and report it.
- Providers at all VMMC sites sharing a catchment area (and ideally, nationally) should have a common understanding of where reporting responsibility lies, to avoid duplicate- and non-reporting.

SECTION 3-TREATMENT GUIDELINES FOR ADVERSE EVENTS IN MALE CIRCUMCISION

GENERAL INFORMATION

- Depending on level of training, knowledge and experience, providers will differ in surgical and AE management skills. Management of some AEs, especially those that are severe, requires an experienced provider. Depending on the AE and the management required, different provider skills may be needed. For example, severe injury to the penis may require management by a plastic surgeon, a complex fistula by an urologist, and tetanus by a physician skilled in intensive care. When it is recommended that an AE be managed by an experienced provider, the provider should be familiar and comfortable with the methods and skills required for managing the client's AE(s). Depending on the type of facility and its staffing, there may or may not be providers with the requisite skills present. In stand-alone facilities and those associated with primary health care facilities, it is likely that providers will NOT have the skills to manage complex or serious AEs and in these instances, clients will require referral. Decisions on whether management should be on-site or there should be client referral should be made by the provider in charge at the site, and should follow existing plans for transfer.
- Prior to discharge from the clinic after MC, all clients should be given a contact phone number to call in the event that they experience an AE or have questions.
- In instances of mobile, outreach or campaign services, trained MC providers may not always remain in the area, and clients with AEs may present to local health clinics staffed by providers not trained in MC or surgical techniques. In such situations, it is important that local providers are made aware that MC services have been provided in the community, are given contact information for the VMMC team, and are asked to call when any client recently circumcised presents with an AE.
- When AEs require surgical repair, this repair, like the circumcision procedure itself, should be done under local rather than general anaesthesia when at all possible. General anaesthesia may rarely be necessary, as in the case of prolonged surgery or extensive debridement, but should only be selected when the procedure cannot be safely performed under local anaesthesia.

EXCESSIVE BLEEDING

MC-related bleeding AEs typically occur in the first 72 hours after the procedure. Bleeding-related AEs occurring after 72 hours are often associated with new trauma to the genital area such as early commencement of masturbation or sexual intercourse, a previously unidentified bleeding vessel, or a bleeding disorder.

Bleeding related to MC is classified according to when the excessive bleeding occurs and by the extent and persistence of bleeding:

- Ongoing intra-operative or immediate post-operative bleeding (classified as A for surgery and A1 for devices)
- Post-operative bleeding (classified as B or C for surgery or A2, B or C for devices), though significant bleeding is unlikely after 72 hours
    - Bleeding related to device circumcision for PrePex and ShangRing may occur at the time of removal of the device and would be classified accordingly (i.e., as category B)

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 haemophilia. 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 such a history in the client or family, MC should not be undertaken under routine conditions. Instead, there should first be consultation with a specialist. It is important to remember that in some people with less severe forms of these bleeding abnormalities, the problem becomes apparent only after 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 first 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. Haemophilia is an inherited disorder that is passed from mothers to sons. In clients with suspected or confirmed haemophilia, 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.**

However, mild or moderate bleeding disorders are not an absolute contraindication to MC. If performed, it should be under tightly controlled conditions with experienced providers in a setting where there is access to blood or clotting factor transfusions.

Particularly in instances of mobile or campaign services, trained MC providers may not always remain in the area for follow-up, and clients with AEs may present to local health clinics staffed by providers not trained in MC or surgical techniques. Clients with bleeding may be particularly vulnerable in such situations. In addition to the general guidance above about ensuring local providers contact the MC team about AEs, local providers also need to be given specific guidance on how manage and refer clients who present with bleeding. Appendix 7 contains a flow chart for management of bleeding that can be distributed to local health care facilities and potentially displayed after VMMC campaigns or mobile services to aid local providers.

It is very important to consider a bleeding abnormality in a client with prolonged or recurrent bleeding, even if there is no prior history of this. In such cases, the client should be referred for specialist medical and surgical care. In the global VMMC programme experience, clients who have had serious consequences from bleeding events have often been those with repeated bleeding episodes and health care visits after MC who were not recognized as having a bleeding disorder. An algorithm for management of bleeding during or immediately after surgery, device placement or removal is included as Appendix 6.

INTRA-OPERATIVE (OR PRIOR TO DISCHARGE FROM CLINIC) BLEEDING OR BLEEDING DURING DEVICE PLACEMENT OR WEARING

Defined as: Oozing/swelling/haematoma/obvious bleeding during or immediately after initial surgery or during device placement and wearing

Intra-operative bleeding that is difficult to control can be due to a number of reasons.

Look for:

- An unidentified bleeding vessel, commonly occurring in the region of the frenulum. This bleeding can be difficult to stop and is best controlled with ligatures and **not** diathermy cautery, since the area of the frenulum and the underlying urethra is vulnerable to cautery-related burns and subsequent fistula development.
- **Caution:** If the identified bleeding area is in the vicinity of the urethra/frenulum, take care not to place the haemostatic sutures too deep, since there is a risk of penetrating the underlying urethra with the sutures, possibly causing a future urethral stricture or fistula.
- If a haematoma has started to form or if there is extravasation of blood into the tissue, the source of bleeding can be difficult to identify. This situation is often associated with a cut blood vessel that has retracted from the plane of the incision, or overly deep dissection with the scalpel blade or dissecting scissors into the highly vascular corpus cavernosa or other deep vascular penile tissue.
- An expanding haematoma is a sign of ongoing bleeding and should be managed as with other acute bleeding.

Excessive bleeding during surgery or immediately thereafter may increase the risk for subsequent wound infection, as bacteria easily reproduce in a hematoma; close follow-up may be needed (e.g., visits at day 2 and day 4 or 5) to ensure that infection does not develop.

Additional and special considerations for devices
With devices, control of bleeding should be managed in the same manner as with surgery. If bleeding occurs when the device is in place and is not easily controlled, the device may need to be removed to identify the source of the bleeding with surgical intervention to complete the circumcision and achieve haemostasis.

PrePex

- Bleeding with placement should not occur as there is no cutting of live tissue
- Bleeding at the time of removal is usually minimal, but can require pressure or, on occasion, placement of sutures for haemostasis

ShangRing

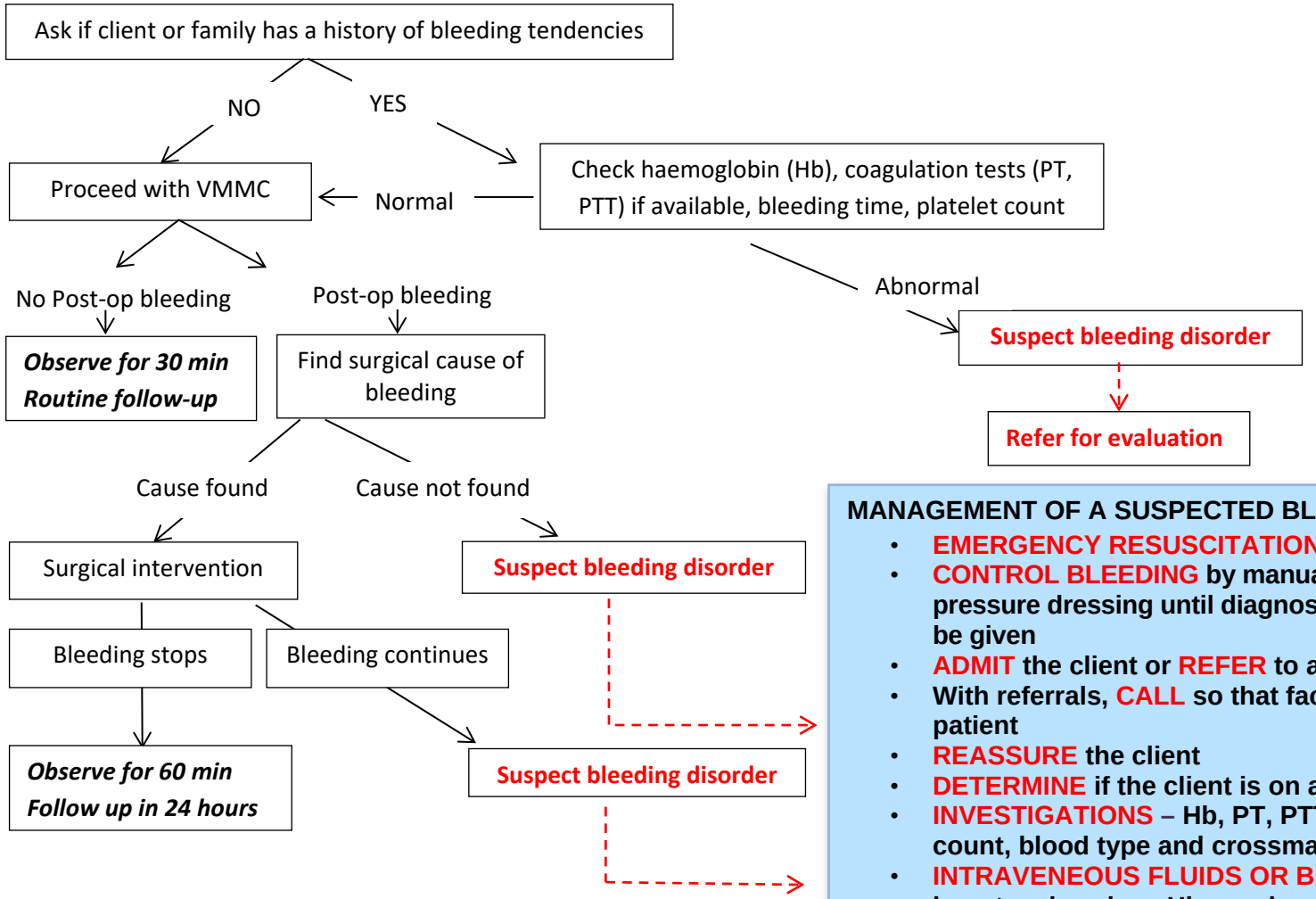
Because foreskin is removed at the time of placement, bleeding can occur with device placement if the ring is not placed properly to attain haemostasis, or if the device becomes displaced. In these instances, bleeding needs to be controlled and an emergency surgical circumcision will likely be needed.

The Algorithm for Management of Acute Bleeding after MC (below and Appendix 6) may be used for evaluation and management of bleeding during or immediately following MC. This algorithm can be adopted as needed by programmes and can be displayed in operating theatres.

In <u>all</u> cases:

- **Stay calm and remember that it is almost always possible to control bleeding with manual pressure onto a gauze swab over the area of bleeding. In cases of severe bleeding it may be necessary to wrap gauze around the penis and to apply manual pressure to the whole circumference of the penis. This technique can be maintained for as long as necessary, for example, while thinking about next steps or calling for assistance, or even during transfer of the client.**
- **Reassure the client.**
- **Monitor the client's blood pressure and heart rate for any signs of shock** (heart rate more than 100 beats per minute, decrease in systolic blood pressure to less than 100 mm Hg).
    - **Note:** Blood pressure may remain normal despite significant blood loss; a fall in blood pressure in a young person often occurs late and is an indication of massive blood loss.

ALGORITHM FOR PREVENTION AND MANAGEMENT OF ACUTE BLEEDING DURING AND AFTER MC



MANAGEMENT OF A SUSPECTED BLEEDING DISORDER:

- **EMERGENCY RESUSCITATION if in hypovolemic shock**
- **CONTROL BLEEDING by manual compression and/or pressure dressing until diagnosis and definitive treatment can be given**
- **ADMIT the client or REFER to a higher facility**
- **With referrals, CALL so that facility can get ready for the patient**
- **REASSURE the client**
- **DETERMINE if the client is on anticoagulant therapy**
- **INVESTIGATIONS – Hb, PT, PTT, bleeding time, platelet count, blood type and crossmatch**
- **INTRAVENEOUS FLUIDS OR BLOOD TRANSFUSION if hypotensive since Hb may be normal after acute bleeding**
- **MANAGE according to the cause—e.g., Vitamin K, clotting factors, FFP, platelet transfusion etc.**

Adapted from JHPIEGO

ADVERSE EVENT	MILD	MODERATE	SEVERE
Description: Excessive Bleeding *Intra-operative or prior to discharge from clinic* **Surgery**	A-BL: Intra-operative bleeding that is more significant than usual or post-operative spotting of the bandage with blood; both easily controlled.	A-BL: 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.	A-BL: 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.
Description: Excessive Bleeding *During device placement or wearing* **Device**	A1/A2-BL: Bleeding during placement that is more significant than usual or spotting of the bandage or clothing with blood; both easily controlled.	A1/A2-BL: Bleeding during placement that requires a pressure dressing to control without surgical re-exploration of the wound or removal of the device.	A1/A2-BL: Bleeding during placement 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.
TREATMENT	**FOR SURGERY** • Apply pressure manually with gauze swab and maintain for 5 minutes. Use a clock to measure the time and do not lift gauze to check until time is done. • Gently remove swab. If bleeding has stopped, reapply the wound dressing. • If bleeding continues, this is a moderate AE. **FOR DEVICE** • Apply pressure manually while taking care not to move or displace device and maintain for 5 minutes. • If bleeding continues, this is a moderate AE.	**FOR SURGERY** • Apply pressure manually with gauze swab and maintain for 5 minutes. Use a clock to measure the time and do not lift gauze to check until time is done. • Gently remove swab and attempt to identify the origin of the bleeding vessel. • If the wound is closed or partially closed, remove sutures since it is easy to miss a bleeding vessel under a fold of skin. • Re-administer local anaesthesia if necessary. • If the bleeding vessel is clearly identifiable, place a suture at that point and tie securely or use electrocautery for haemostasis if the bleeding area is not in the vicinity of the frenulum.	**FOR SURGERY** • **Refer** to the higher-level facility. • Apply manual pressure to control bleeding during transfer of the client. • Establish intravenous access and administer crystalloid replacement fluids (e.g., sodium chloride) of 1–2 litres. • Re-exploration of the wound should be performed with good lighting and removal of all sutures so that there can be thorough inspection of the wound. • If there is excessive bleeding from the frenular artery, an underrunning haemostatic stitch should be used to occlude the artery. Avoid biting too deeply, which can damage the urethra. • If one or two re-explorations of the

ADVERSE EVENT	MILD	MODERATE	SEVERE
		• If the bleeding vessel is not identifiable, under-run the bleeding area by starting at a dry point and insert continuous sutures which cross the bleeding area, ending with a knot at a dry part of the surface. • For difficult frenular bleeds, place an additional vertical mattress suture. Great care is needed not to place the suture too deeply, because the urethra is near to the surface skin and can easily be damaged. • **Be prepared to call for a more experienced provider and/or refer (see severe AE management).** **FOR DEVICE** • When applying any pressure or pressure dressing to the wound, take care not to displace or move the device. • Unless the source of bleeding can be clearly identified and controlled with pressure, it is likely that the device will need to be removed and a surgical circumcision performed; this will be classified as a severe event.	wound have failed to identify a distinct bleeding vessel but the bleeding continues, suspicion for a bleeding disorder should be high. In this case, further re-exploration is unlikely to benefit the patient and may worsen bleeding. The focus should be on correcting clotting deficiencies. **ADVANCED MANAGEMENT IN BLEEDING DISORDERS** For clients with likely bleeding disorders treated in high-level facilities: • In those who respond well to factor VIII, continue infusions for 7 days to allow healing and prevent rebleeding. • Re-exploration should be avoided if possible, but if necessary (e.g. to remove clots), pretreatment with appropriate clotting factors can help prevent bleeding. Consult hematology. • Hematology consultation by phone may be sufficient and helpful, if not available on site. **FOR DEVICE** • As above for surgery. • The management is the same as for severe bleeding after surgery except that it will probably be necessary to remove the device and convert to a surgical circumcision.

POST-OPERATIVE EXCESSIVE BLEEDING OR EXCESSIVE BLEEDING DURING DEVICE WEARING, DURING DEVICE REMOVAL OR AFTER DEVICE REMOVAL

Defined as: Oozing/obvious bleeding after discharge from MC clinic or during or after device removal

- Prior to discharge from the clinic, all clients should be given a contact phone number to call in the event that they experience an AE or have questions. Clients should be instructed that if they experience any post-operative bleeding (or any other AE), they should call a MC provider using the contact number.
- Mild post-operative bleeding may be caused by removal of dressings, leading to some displacement/disruption of the suture margin clot or scab formation. This bleeding is usually very slow, from an identifiable location where the healing suture margin clot/scab has been disrupted. Bleeding caused by removal of a dressing or cleaning of a wound can be prevented or decreased by wetting the dressing with sterile water or saline prior to removal and avoiding removing any clot/scab.
- Moderate to severe post-operative bleeding usually presents from 6 hours after surgery through the first post-operative day, but can occur even later. It may be due to bleeding of a cauterized or sutured vessel, or a previously unidentified vessel becoming disrupted by an erection, trauma, or other external event to the area. Look for significant bleeding or a regular stream of fresh blood from the suture margin or wound, soaking dressings or underwear. If this bleeding is contained or partially contained by the suture margin or scab covering the wound, there may be accompanying swelling or underlying haematoma. This presents as swelling, bleeding, or both.
- If a client returns with a complaint of bleeding and bleeding is controlled, he should be scheduled for follow-up the next day. If a clinic visit is not possible, there should be follow-up by phone to make sure that bleeding has not recurred.
- **Any bleeding or haematoma that recurs (presents more than once) could indicate a bleeding abnormality and should be closely followed by an experienced provider trained in MC or referred for further evaluation.**
- If a client presents with post-operative bleeding, he (or his guardians, in case of a minor) should re-questioned about a personal or family history of bleeding in the event that this information was not initially collected or that because of a desire to get MC, this information was not disclosed. In the event that there is now a family or personal history of bleeding, consider referral, even if haemostasis is achieved.
- Fresh, noticeable active bleeding not controlled by a pressure dressing requires re-operation, or referral if re-operation at the site is not possible.
- Also see “Other Adverse Events” if there is swelling or haematoma.
- An algorithm for management of haematoma is included in this guide under the chapter “Other Adverse Events: Excess Swelling of Penis/Scrotum including Haematoma, Problem with Voiding (Urinating), Other” and as Appendix 8.

Additional and special considerations for devices

- If heavy bleeding is encountered at device removal, application of pressure or placement of sutures for control may be needed.
- In general, all bleeding after removal of device should be handled in the same manner as bleeding after surgical circumcision.

PrePex

- At PrePex removal, oozing may be seen when necrotic tissue is separated from the underlying healing wound. If this is a small amount of blood and the bleeding is easily controlled not requiring pressure, it does not need to be classified as an AE.
- While removing the necrotic foreskin with Harvey wire scissors, acute injury to underlying tissue is also possible, and bleeding can occur and would be classified as a category B adverse event.

ADVERSE EVENT	MILD	MODERATE	SEVERE
Description: Excessive Bleeding *Post-operative* **Surgery**	B/C-BL: 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.	B/C-BL: 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.	B/C-BL: Bleeding that requires surgical re-exploration, hospitalization, or transfer to another facility; or any case where blood transfusion or intravenous fluid is necessary.
Description: Excessive Bleeding *During or after device removal* **Device**	B/C-BL: Small amount of bleeding from wound with no active bleeding and is controllable with new dressings or 5–10 minutes of manual pressure.	B/C-BL: 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 exploration of the wound.	B/C-BL: Bleeding that requires surgical exploration, hospitalization, or transfer to another facility; or any case where blood transfusion or intravenous fluid is necessary.
TREATMENT	**FOR SURGERY** • Control with new dressings or 5–10 minutes of manual pressure. Use a clock to measure the time and do not lift gauze to check until time is done. • Apply a light pressure dressing and observe the client for 30 minute, using a clock to measure the time. • Review in 24 hours. **FOR DEVICE** • Management as above for surgery.	**FOR SURGERY** Note that haematomas are often best managed conservatively even when they are quite large (see section on haematoma) • Apply pressure manually with gauze and maintain for 5 minutes. Use a clock to measure the time and do not lift gauze to check until time is done. • Gently remove swab and attempt to identify the origin of the bleed. • If provider(s) have sufficient experience and expertise, administer local anaesthesia and examine the wound. • If bleeding vessel is clearly identifiable, place a suture at that point and tie securely. • If the bleeding vessel is not identifiable under-run the bleeding area by starting at a dry point and insert continuous	**FOR SURGERY** • If the pressure dressing is significantly soaked with blood, the client will require surgical re-exploration. • Apply manual pressure/compression over gauze swab to control bleeding. • Establish intravenous access and administer crystalloid replacement fluids of 1–2 litres. • If provider(s) have sufficient experience and expertise, administer local anaesthesia and explore the wound. • **FOLLOW UP** initially daily until the clinical team assesses client's progress as satisfactory. • If sufficient expertise to manage client not available on site, **REFER** to a higher-level facility. • Apply manual pressure to control bleeding during transfer of the client. • Keep client supine to avoid hanging

ADVERSE EVENT	MILD	MODERATE	SEVERE
		sutures which cross the bleeding area, ending with a knot at a dry part of the surface. • Observe the client for at least one hour and re-inspect the dressing. • Give the client the emergency contact details of the provider on call in case bleeding resumes. • **FOLLOW UP** initially daily until the clinical team assesses client's progress as satisfactory. **FOR DEVICE** • Management as above for surgery.	penis that can result in penile engorgement and further bleeding. • If one or two re-explorations of the wound have failed to identify a distinct bleeding vessel but the bleeding continues, suspicion for a bleeding disorder should be high. In this case, further re-exploration is unlikely to benefit the patient and may worsen bleeding. The focus should be on correcting clotting deficiencies. **ADVANCED MANAGEMENT IN BLEEDING DISORDERS** For clients with likely bleeding disorders treated in high-level facilities: • In those who respond well to factor VIII, continue infusions for 7 days to allow healing and prevent rebleeding. • Re-exploration should be avoided if possible, but if necessary (e.g. to remove clots), pretreatment with appropriate clotting factors can help prevent bleeding. Consult hematology. • Hematology consultation by phone may be sufficient and helpful, if not available in-house. **FOR DEVICE** • Management as above for surgery.

INFECTION

Defined as: The condition resulting from the invasion of the body by pathogenic microorganisms

Infection-related AEs may present as soon as the second day post-operatively or post-device placement, and typically present in the first two weeks following foreskin removal (timing classification B or C for surgery, C for devices). However, problems related to effects of severe wound infections can present months, or even years, later. Wound infection severity can fall anywhere on a broad spectrum ranging from mild/moderate manifestations of wound infections, to serous wound discharge and suture margin infections, to severe wound disruption secondary to infection, abscess formation, areas of wound or skin necrosis, disfigurement and sepsis. Mild infections can be treated conservatively with local wound cleaning and dressing changes. Moderate or severe infections should be treated with systemic antibiotics. Topical antibiotics usually should not be used.

NOTE: There are separate classifications for treatment of wound disruption and scarring/disfigurement, which can often occur with wound infection, later in this section.

Look for:

- Suture or wound margin discharge that is serous or frank pus.
- Small areas of yellow slough, often around a suture itself or the wound margin, especially the area of the frenulum.
- Blistering around the incision or near the wound margin.

Inquire about:

- When the signs of infection were first noted.
- Wound hygiene and cleaning practices.
- Pain. Post-operative pain usually improves following MC. Pain that is getting worse might be a sign of infection.
- Self-administered treatment, including use of home or traditional remedies on the circumcision wound.

A localized swollen, fluctuant area (often extremely tender to palpation), warm affected area, offensive odour, and/or thick yellow discharge may indicate the presence of an abscess, which may require surgical drainage and treatment with antibiotics**.** If there is cellulitis, marking the line of erythema with a pen at the time of diagnosis and repeatedly at set intervals such as 1–2 hours, along with photographs if possible, may help providers determine whether the infection is advancing or improving with treatment, and how quickly.

All infected wounds should be examined for the presence of a fistula, as on occasion wound infection can lead to the formation of a fistula. Clients may present with complaints of leaking or spraying of urine. Initial treatment in such a case should be the same as if fistula were not

present. **In addition, in all instances when there is the presence of a fistula, there should be prompt referral to a specialist for evaluation and repair as needed.**

A rare but serious complication of circumcision may be necrotising fasciitis of the genitals. This is sometimes also called Fournier gangrene. This infection usually involves multiple organisms including anaerobic bacteria, can advance rapidly along tissue planes, results in necrosis of large areas of tissue, and has significant morbidity and mortality. Important points around this infection include:

- Necrotising fasciitis is a life-threatening infection where the infection can spread over hours.
- Necrotising fasciitis may be characterized by intense pain and tenderness over the involved skin.
- If necrotising fasciitis is suspected, there should be **urgent** referral to a center with capacity to manage this condition (often a district or larger hospital). This infection spreads very rapidly; a history of normal healing the day or two before presenting with evidence of severe infection might be a clue for the provider to this life-threatening emergency.
- **Mark the line of cellulitis** so as to monitor advancement of infection.
- A multimodal approach is key, centered around early and aggressive debridement and broad-spectrum antibiotics that are effective against anaerobes.
- Many cases require multiple debridement procedures.

In any case of a wound infection, especially where there appears to be presence of anaerobes as evidenced by odour, and if the client was not vaccinated for tetanus at the time of MC or already up-to-date, consider providing a tetanus booster if available and per national policy. (This will not completely mitigate risk of tetanus, but could prove useful in those who previously received a complete primary series).

Additional and special considerations for devices

Infections with use of devices are classified as A2 (during wearing) or C (after removal). Infection noted at the time of removal should be classified as A2.

If an infection develops while a device is in place, it may be deemed necessary to remove the device. As there is little experience with this situation, there is no standard practice for this decision. Depending of the stage of wound healing or foreskin necrosis (in the case of PrePex), the provider will also need to decide if surgery or other interventions such as debridement are needed.

With device wounds, which heal by secondary intention, white or yellowish discharge can develop over the wound during normal healing. This granulation tissue may sometimes be confused with infection. The presence of warmth, pain and erythema (redness) are signs that can distinguish true infection.

PrePex

- With the PrePex device, in most men there is an odour resulting from the necrosis of the foreskin while the device is in place. In some cases, the odour can be intense and offensive. It is probably caused by anaerobic growth in the space between the necrotic foreskin and underlying tissue, and is not an infection. As infections caused by anaerobic bacteria can also produce a similar odour, there may be confusion between the necrotic process and infection when this device is in place. Infection is usually accompanied by warmth, pain, and erythema, which can be used to distinguish infection from the necrotic process.
- There have been several cases in which premature sloughing of some layers of the foreskin has been observed while PrePex is in place. The occurrence of this is even rarer than device displacement, so there is little clinical information to date. In several cases, part of the inner mucosa has separated from the rest of the foreskin and was seen protruding from the end of the foreskin. In a single case, this protrusion appeared as a urine-filled sac. The appearance of this is alarming but involves only the necrosing foreskin; live tissue is not affected. While this is not listed as a defined AE in this guide, it should be reported so that additional data on this rare event and its management can be gathered. If urination is obstructed, surgical circumcision may be necessary.

TETANUS

Tetanus is an acute and frequently fatal disease caused by a neurotoxin produced by the organism *Clostridium tetani*. This bacterium is commonly found in the environment in places such as warm, moist soil. The bacteria may also be found in the intestinal tract of humans and animals.

There have been rare reports of tetanus associated with both surgical and PrePex MC. Overall, the risk of tetanus following circumcision appears to be extremely low. However, the risk of tetanus, both in the context of MC and in general, may be increased by low tetanus immunisation primary series or booster coverage in adolescent and adult males, resulting in low rates of protective immunity. Following circumcision, applying home remedies that contain animal dung, plants or soil could increase the risk of tetanus because these may be contaminated with *C. tetani* spores. In several of the tetanus cases associated with MC, home remedies were applied to the MC wound. This underscores the importance of counselling clients about proper wound care, including not applying any substances to the MC wound unless instructed to do so by providers.

Diagnosis of tetanus is based on typical signs and symptoms, including:

- Headache
- Jaw cramping
- Sudden, involuntary muscle spasms, including in the neck, shoulder, or chest
- Painful muscle stiffness all over the body
- Difficulty swallowing
- Seizures
- Fever and sweating

- Hypertension
- Tachycardia (fast heart rate)

For more information, see: http://www.cdc.gov/tetanus/about/symptoms-complications.html

Diagnosis or suspicion of tetanus is a medical emergency requiring hospitalization at a facility capable of delivering a high level of supportive care, **including respiratory support with a ventilator. Immediate treatment with human tetanus immune globulin (TIG) is an important part of management**. Drugs to control muscle spasms, aggressive wound care and antibiotics are also important components of the management (http://www.cdc.gov/tetanus/about/diagnosis-treatment.html). Additional details on treatment of tetanus have been published by WHO (Current recommendations for treatment of tetanus during humanitarian emergencies: http://www.who.int/diseasecontrol_emergencies/publications/who_hse_gar_dce_2010.2/en/). Any case of suspected or confirmed tetanus should be transferred **immediately** to a facility capable of providing intense support, **even if such support is not required at the time.** Waiting until symptoms worsen and there is an acute need for support could result in death of the client. Transportation may be hazardous if transport vehicles are not well equipped to handle a sudden change of status, such as development of convulsions or respiratory distress that may commence en route. Communication with the referral facility, with agreement on a safe transfer plan, is critical.

Each tetanus case should be thoroughly investigated and reviewed for association with MC, and reported to the WHO by the ministry of health. Device manufacturers should be informed of any case after device use.

In settings where there is incomplete coverage with an infant primary tetanus series or where tetanus boosters are not up to date, the population eligible for MC may be not be protected from tetanus. WHO and PEPFAR have proposed that ministries of health develop policies regarding use of tetanus vaccination and boosters in the context of MC, and have provided recommendations (http://www.who.int/hiv/pub/malecircumcision/tetanus-male-circumcision/en/).

In a person who has received no prior tetanus immunisation, a single dose of vaccine serves to prime the immune system but does not result in a protective antibody level, and thus there is not protection from tetanus. Even in those with at least one prior immunisation who receive a subsequent dose, substantial levels of antibody may not be seen until 7 days after the vaccination, with a maximum level by 14 days. Given this timing, revaccination of previously vaccinated clients at the time of circumcision also cannot be relied on to protect clients from tetanus. **Note: There have been at least 3 cases of tetanus in clients who received a single dose of a tetanus toxoid-containing vaccine (TTCV) at the time of either surgical circumcision or PrePex placement.**

Based on review of the most recent available program data, as of July 2016, WHO released a technical consultation update (http://www.who.int/hiv/pub/malecircumcision/male-circumcision-2016-update/en/). **This advises that for circumcision with a device method that requires that the foreskin remains in situ for several days before it is removed, all clients without a documented history of**

appropriate tetanus immunization receive two doses of TTCV prior to device placement, at least four weeks apart, with the second falling at least two weeks before placement. Clients with documentation of three infant doses or one dose during adolescence or adulthood should receive a booster at least two weeks before device placement. Those with five or six documented lifetime doses given on appropriate schedules do not need additional immunization. For surgical circumcision, no changes have been made to the 2015 WHO meeting report (http://www.who.int/hiv/pub/malecircumcision/tetanus-male-circumcision/en/) recommending that Ministries of Health develop TTCV delivery strategies based on national TTCV schedules, practices and coverage and tetanus burden, ensuring that clients without documentation of sufficient coverage receive at least one dose of TTCV at the time of VMMC. While this dose is not expected to provide protection from tetanus during the VMMC healing period, it may help to improve the client's general protection against tetanus.

With time, additional data may become available on the risk of tetanus and circumcision with surgery or with specific device(s). Implementers and programme managers need to be aware of the latest information from WHO on device use for circumcision, available at http://www.who.int/diagnostics_laboratory/evaluations/PQMCdevices_list/en/, as well as the latest versions of device manufacturers' instructions for use (IFU). At the time of writing, IFU for PrePex and ShangRing were available at the following links:

- PrePex: http://prepex.com/device-overview/user-manual/
- ShangRing: http://www.who.int/hiv/topics/malecircumcision/prequal_mc_devices_2015.pdf (*IFU at end of document*)

Regardless of the approach taken to immunisation or the circumcision method, clean care including appropriate skin preparation and wound care counseling for clients is crucial, including the importance of not placing substances including traditional remedies on the wound, as this is a risk factor for tetanus.

ADVERSE EVENT	MILD	MODERATE	SEVERE
CONSIDER OBTAINING SERIAL PHOTOGRAPHS TO DOCUMENT ADVERSE EVENT AND PROGRESS			
Description: Infection **Surgery**	B/C-IN: Erythema or traces of serous discharge or infective process noted at wound margin. No intervention other than improved wound hygiene.	B/C-IN: Discharge from the wound, painful swelling with erythema, or elevated temperature that requires use of oral antibiotics.	B/C-IN: Cellulitis or abscess of the wound, or infection severe enough to require surgical intervention, hospitalization, or intravenous or intramuscular antibiotics.
Description: Infection **Device**	A2/C-IN: Erythema or traces of serous discharge or infective process noted at wound margin. No intervention other than improved wound hygiene.	A2/C-IN: Discharge from the wound, painful swelling with erythema, or elevated temperature that requires use of oral antibiotics.	A2/C-IN: Cellulitis or abscess of the wound, or infection severe enough to require surgical intervention, hospitalization, or intravenous or intramuscular antibiotics.
TREATMENT	**FOR SURGERY** • Explain and emphasize importance of keeping the wound clean for favourable outcomes in the recovery/healing period. • Consider daily dressing changes for improved wound hygiene. • Consider treating localized areas of suture margin infection with local care including frequent dressing changes and cleaning. • Topical antibiotics should not be used. • Consider providing a tetanus booster if available and per national policy. **FOR DEVICE** • Management as above for surgery. **Any client with symptoms suggestive of tetanus should be immediately transferred to a high level facility for support and tetanus immune globulin should be administered as soon as possible.**	**FOR SURGERY** • Explain and emphasize importance of keeping the wound clean for favourable outcomes in the recovery/healing period. • If significant discharge and pus from the suture margin/wound, or marked erythema of surrounding tissue, or elevated temperature, add oral, locally-appropriate broad spectrum antibiotics such as amoxicillin/clavulanic acid, or in accordance with national guidance or locally available drugs. • **FOLLOW UP** initially on a daily basis and once improvement is noted, at 2-3 day intervals until healing is complete. • **Advise any client with infection to contact provider if pain or discharge worsens or he develops other symptoms such as fever.** • Consider providing a tetanus booster if available and per national policy.	**FOR SURGERY** • Infections accompanied by systemic signs such as fever, chills, and constitutional symptoms should be treated with locally appropriate, broad spectrum intravenous or intramuscular antibiotics according to national guidelines. • Elevate the penis by strapping it up against the abdominal wall. • For infections that do not improve on treatment, swab infected area and send for microbiological identification and drug sensitivity testing, where laboratory services are available. • **Refer** for treatment and monitoring. If debridement or abscess drainage are needed, intravenous or intramuscular antibiotics and referral to a surgical provider will be needed. • In the case of an abscess, if a delay of more than 6 hours is expected before the client is able to reach a referral location, it

ADVERSE EVENT	MILD	MODERATE	SEVERE
		FOR DEVICE • Management as above for surgery. • Determine if there is need to remove the device early as part of the management of the infection, keeping in mind the risk of bleeding when a device is removed early. Depending of the stage of wound healing or foreskin necrosis (in the case of PrePex), the provider will need to decide if surgery is needed. **Any client with any signs of a necrotising infection such as rapidly advancing erythema or infection should be suspected of having a necrotising infection and considered for referral and evaluation for aggressive surgical debridement.** **Any client with symptoms suggestive of tetanus should be immediately transferred to a high level facility for support and tetanus immune globulin should be administered as soon as possible.**	may be useful to release 1–2 sutures in the hope that pus will drain. If no pus drains, do not further manipulate. The use of non-absorbable suture to tie or suture blood vessels can cause an abscess to persist. • Consider providing a tetanus booster if available and per national policy. **FOR DEVICE** • Management as above for surgery. • Determine if there is need to remove the device early as part of the management of the infection, keeping in mind the risk of bleeding when a device is removed early. Depending of the stage of wound healing or foreskin necrosis (in the case of PrePex), the provider will need to decide if surgery or wound closure is needed. **Any client with rapidly advancing erythema or infection should be suspected of having a necrotising infection, and considered for referral and evaluation for aggressive surgical debridement.** **Any client with symptoms suggestive of tetanus should be immediately transferred to a high-level facility for support, and tetanus immune globulin should be administered as soon as possible.**

WOUND DISRUPTION

Defined as: The opening of a wound along surgical suture the wound margin, also known as wound dehiscence

- Surgical wound disruption may follow the unravelling of a suture (possibly poorly placed or tied), premature dissolution of an absorbable suture, or infection of the wound that involves swelling and separation of the edges. Too-tight knotting of the suture can cause ischaemia of the wound edges that may also later cause wound disruption. Less frequently, wound disruption may follow trauma (e.g., early resumption of sexual activity).
- Wound disruption associated with infection should be managed as described below and additionally as outlined in the chapter on infection.
- A clean, uninfected, disrupted wound can usually be re-sutured less than 48 hours after circumcision for an improved cosmetic appearance.
- Older clean disrupted wounds can sometimes also be re-sutured, including those in which infection has been successfully treated. But usually after 48 hours, disrupted wounds are contaminated or may have obvious infection. In these cases it is better not to attempt suture closure, but instead to leave the wound open to heal from within (by secondary intention). Placing sutures to close such a wound often results in infected sutures which ‘cut out’ through the skin, and a longer wound healing time than if the wound were left open. It requires experience and judgement to tell whether an older disrupted wound can be sutured. Clients can be reassured that the cosmetic appearance of a disrupted wound which is left open usually improves after a year.

Wound disruption associated with surgery is classified as B or C only.

Additional and special considerations for devices

- Device wounds heal by secondary intention and are different in appearance from post-surgical circumcision wounds, which heal by primary intention. By definition, wounds that heal by secondary intention are not closely apposed and there is a gap between wound edges during normal healing. This does not count as wound disruption.
- Wound disruption in the context of a device circumcision should be determined by an increasing distance between wound edges, with exposure of deeper tissues at the base of the wound.
- The severity of device wound disruption is classified based on width, rather than on length along the suture line as with surgical wound disruption.

Wound disruption associated with devices is classified as C only.

ADVERSE EVENT	MILD	MODERATE	SEVERE
CONSIDER OBTAINING SERIAL PHOTOGRAPHS TO DOCUMENT ADVERSE EVENT AND PROGRESS			
Description: **Wound Disruption** **Surgery**	B/C-WD: Wound disruption but not extensive enough to require suturing for wound closure (<1.0 cm in length).	B/C-WD: Wound disruption extensive enough to require suturing or other clinical intervention but not surgery (≥ 1.0 cm in **length**).	B/C-WD: Surgical re-exploration or repair is required, or referral/transfer to another facility or hospitalization is required.
Description: **Wound Disruption** ***after removal*** **Device**	C-WD: Wound disruption but not extensive enough to require suturing for wound closure.	C-WD: Muco-cutaneous gap ≥ 1.0 cm in **width**, but no exposure of deeper tissue	C-WD: Wound disruption exposing tissue deeper than subcutaneous tissue or requiring surgical intervention such as suturing or debridement.
TREATMENT	**FOR SURGERY** • Generally, dehiscence measuring less than 1.0 cm in length (not width) does not require additional sutures. • Reassure client that the penis heals well and no further treatment is needed. Advise on adequate wound hygiene and follow-up. **FOR DEVICE** • A gap between wound skin edges that increases in size from the time of device removal and where there is no exposure of underlying tissue does not constitute an AE. • Management as above for surgery.	**FOR SURGERY** • If circumcision was <48 hours ago and there are no signs of infection, apply additional sutures. • If circumcision was over 48 hours ago but wound appears clean or any infection has been successfully treated, experienced providers can consider resuturing. Leaving wound open may be preferable. • If wound disruption and infection present, clean the wound, apply daily dressing and treat with oral antibiotics such as amoxicillin/clavulanic acid, or in accordance with national guidance or locally available drugs. **FOR DEVICE** • Gap is measured as distance between wound edges for devices, not along the length of the wound as with surgery. • Management as above for surgery.	**FOR SURGERY** • **Refer** for further treatment in a surgical unit. **FOR DEVICE** • Management as above for surgery.

PAIN

Defined as: An unpleasant sensation related to the circumcision surgery, during either the surgery itself or recovery from the surgery

Pain is a difficult and subjective sensation to classify. People have different thresholds of pain, so trying to classify pain as mild, moderate, or severe is challenging. A limited amount of pain is also a normal event associated with any surgery; not all pain constitutes an adverse event.

INTRA-OPERATIVE PAIN

Surgical MC results in pain and requires control during the procedure with local anaesthesia. Usually the only pain experienced is that of the injection itself. If the local anaesthetic agent(s) is under-dosed or the procedure is lengthy, additional anaesthetic may be needed in order to manage client pain adequately. If higher-than-recommended doses of local anaesthetic are required to control pain, this may be due to inappropriate injection technique leading to administration of the drug into a blood vessel rather than into the local area, or the medication may be expired, or be of poor quality and not contain the amount of anaesthetic stated on the label.

Additional and special considerations for devices
As with surgery, use of devices for MC results in pain, and pain control is required. The course of pain with devices differs somewhat from that associated with surgery, and the pain seen with the PrePex device is different from that seen with the ShangRing.

PrePex

- As there is no cutting of vital tissue at the time of PrePex placement, there is little to no pain at that time. Mild pain often develops in the first few hours after placement and this can be controlled by the use of topical anaesthetic applied at the time of device placement. **Complaints of pain at the time of placement should be a signal to look for device misplacement**. Pain while wearing the device has been reported and in rare cases has prompted early removal. Pain at the time of removal is reported by the majority of clients and can be severe. While this pain often lasts only seconds, up to 30 minutes of pain post-removal has been reported.

ShangRing

- As currently performed, the ShangRing requires the use of injectable anaesthesia because the foreskin is removed during placement. As with surgery, there is pain associated with the injection of anaesthesia, but there should not be additional pain during the procedure.

With devices, a visual analogue score (VAS) is often used to rate pain at a single moment in time, with 0 being no pain and a score of 10 being the worst pain imaginable. Classification of severity may be based on this score. This differs from the classification method for pain associated with surgery, which is based on disability over time, making it somewhat difficult to compare pain between the two methods. Intraoperative pain (pain at placement) associated with devices is classified as A1 only.

ADVERSE EVENT	MILD	MODERATE	SEVERE
Description: **Pain** ***Intra-operative or prior to discharge from clinic*** **Surgery**	A-PA: Client expresses discomfort, however is able to remain still and cooperate for the procedure. No additional local anaesthetic is required.	A-PA: Pain requiring additional local anaesthesia	A-PA: Pain not responsive to additional local anaesthesia.
Description: **Pain** ***Intra-operative or prior to discharge from clinic*** **Device**	A1-PA: Client expresses discomfort, however is able to remain still and cooperate for the procedure.	A1-PA: Client expresses discomfort and is not able to cooperate well with procedure.	A1-PA: Client rates pain as very severe.
TREAT	**FOR SURGERY** • Mild pain and/or discomfort is expected when one gets an injection, and therefore not medically significant, reassure client. **FOR DEVICE** • Mild pain and/or discomfort is expected and therefore not medically significant, reassure client.	**FOR SURGERY** • Check the local anaesthetic vial with use of injectable anaesthesia (correct substance, expiration date). • Give additional local anaesthetic while remaining within maximum safe dose. **FOR DEVICE** • Check for misplacement of device. • In the case of ShangRing, give additional local injectable anaesthetic while remaining within maximum safe dose.	**FOR SURGERY** • Check the local anaesthetic vial with use of injectable anaesthesia (correct substance, expiration date). • If there is severe pain during anaesthetic injection or after administration, postpone procedure to another day, and investigate the cause of the pain. **FOR DEVICE** • Check for misplacement of device. • Explore reasons for pain/pain perception. • Postpone procedure to another day and investigate the cause of the pain.

POST-OPERATIVE PAIN

The average surgical MC client will report pain starting 2-3 hours after surgery and for at least the first 2–3 days after his operation. This pain typically subsides with the use of over-the-counter oral analgesia and should not routinely disrupt sleep. Pain may intensify with night-time or morning erections and cause the client to awaken. This is normal as long as the pain subsides when the erection resolves. Clients should experience a daily general improvement in pain after the operation, with little to no pain or discomfort after 7–10 days. In cases of worsening pain, suspect an underlying problem such as infection.

Pain is regarded as outside of normal parameters and should be classified as an AE when one or more of the following occur:

- Pain does not resolve even with analgesia
- Sleep is significantly disrupted due to pain
- Mobility is impaired by pain and the performance of daily tasks is significantly restricted more than 48 hours after surgery
- Pain/discomfort has not improved significantly 7–10 days after surgery
- Pain gets progressively worse, not better, after surgery or device removal
- Pain is associated with another type of AE, such as infection

Providers need to use their experience, training and these guidelines to decide if there is abnormal pain beyond the expected pain associated with MC or if the pain is due to another AE, such as infection. Pain due to infection may be characterized as that which initially improved in the first days following the procedure but then worsened as the infection developed.

Additional and special considerations for devices
Pain that occurs during device removal (B) is found in the post-operative chart below.

ADVERSE EVENT	MILD	MODERATE	SEVERE
Description: **Pain** ***Post-operative*** **Surgery**	B/C-PA: Client complaints of pain, not requiring more than standard post-operative analgesics and considered within normal thresholds associated with surgery.	B/C-PA: 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.	B/C-PA: 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**.**
Description: **Pain** ***during wearing, at removal and after removal*** **Device**	A2/B/C-PA: Client complaints of pain, not requiring more than standard post-operative analgesics and considered within normal thresholds associated with surgery	A2/B/C-PA: 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 programmes that utilize a visual analogue scale (VAS) for rating severity, a VAS score of 5-7 (on a 1-10 scale).	A2/B/C-PA: 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 programmes that utilize a visual analogue scale (VAS) for rating severity of pain, a VAS score of 8-10 (on a 1-10 scale).
TREATMENT	**FOR SURGERY** • Reassure client and administer oral analgesic agents such as Paracetamol (Acetaminophen) or Ibuprofen. **FOR DEVICE** • Management of as above.	**FOR SURGERY** • Look for possible cause of pain, (e.g., another AE), and treat that AE. • Review the analgesia being used (dosage, frequency, drug expiration). • Reduce ambulation. **FOR DEVICE** • Management as above for surgery. • In some instances, management of device-related pain may include early removal of device. Depending of the stage of wound healing or foreskin necrosis (in the case of PrePex), at the time of removal, the provider will need to decide if surgery or wound closure is needed.	**FOR SURGERY** • Look for possible cause of pain, (e.g., another AE), and treat that AE. • Review the analgesia being used (dosage, frequency, drug expiration). • **Refer** to specialist. **FOR DEVICE** • Management as above for surgery. • In some instances, management of device-related pain may include early removal of device. Depending of the stage of wound healing or foreskin necrosis (in the case of PrePex), at the time of removal, the provider will need to decide if surgery or wound closure is needed.

SCARRING/DISFIGUREMENT/POOR COSMETIC RESULT; INJURY TO PENIS

Multiple events can lead to scarring, poor cosmetic result, or injury. These include poor surgical technique, post-operative infection and poor wound healing.

In this section, there are several definitions and recommendations for management given for different conditions, including:

- Insufficient skin removal
- Injury to penis (including the glans, shaft, urethra)
- Excess skin removal
- Scarring/disfigurement
- Torsion of the penis

All of these should be reported under the appropriate AE of scarring/disfigurement/poor cosmetic result. In the cases of scarring/disfigurement, torsion of the penis and insufficient skin removal, full assessment cannot be made until more than 7 days after surgery, and therefore all cases are classified as C **for both surgery and devices**. Injury to the penis and excess skin removal can be noted at the time of surgery or thereafter, and can be classified as **A, B, or C for surgery**; or **A1, A2, B or C for devices**.

These AEs are very rare and have not yet been observed after device-based circumcision.

SCARRING/DISFIGUREMENT

Defined as: A transient or permanent negative alteration in the appearance of the penis

This can only be classified as **C for both surgery and devices**, as accurate assessment of scarring is not possible before 7 days.

Scarring/disfigurement ranges from mild scarring to a gross distortion of the penis during or after the healing process. Usually the client presents after wound healing, complaining about appearance of the penis, or the provider notes the disfigurement at the follow-up visit. Always examine the client with maximum privacy and in good light, preferably natural. Determine if the problem is present all of the time or only evident during penile erection. If the problem is only evident during erection, make arrangements for the client to be examined with an erection (referral to specialist urologist). Having the client take a photo of his penis when he has an erection (such as upon waking in the morning) can be very helpful in the assessment of penile deformity or any other erection-related abnormality.

AEs that may lead to skin loss or large skin defects can lead to scarring during healing. Early referral for skin grafting in these cases can decrease scar formation.

In discussing both scarring/disfigurement, keloid formation (excessive and disfiguring scar formation) needs to be considered. Keloids are extremely rare on the penis; however, cases have been recorded in areas where there is hair (mid-shaft to base of the penis). Penile skin does not have hair in the areas involved in circumcision, and no cuts should be made in, or devices placed over, areas that have hair. If a keloid is suspected, **repair or removal should be performed only by an expert,** since further surgery could lead to increased scar formation.

Excessive tension from sutures can create a ridge with grooves where the sutures were placed. Most ridging will resolve spontaneously by 12 months; however, when the suture line is not straight, there can be persistent ridging, and management should be as described below. Subcutaneous nodules may also form on the shaft of the penis, caused by excess suture material that has been used to stop bleeding or by inclusion of too much tissue in a haemostatic suture.

There have been reports of a cosmetic effect of uneven or jagged skin edge with the dorsal slit technique of MC, as the foreskin is trimmed around the glans using multiple cuts with dissection scissors. This cosmetic result can be mitigated with careful trimming of any skin tags on the inner edge of the foreskin. Care must be taken to leave approximately 5 mm of skin proximal to the corona and not to cut deeper tissue.

Additional and special considerations for devices
None.

ADVERSE EVENT	MILD	MODERATE	SEVERE
CONSIDER OBTAINING SERIAL PHOTOGRAPHS TO DOCUMENT ADVERSE EVENT AND PROGRESS			
Description: Scarring **Surgery**	C-SD: Complaints by client in the absence of discernible abnormal scarring/disfigurement.	C-SD: Discernible but re-operation not required. Usually noticed first by the client and reported to the provider.	C-SD: Discernible and requires re-operation or referral/transfer to another facility.
Description: Scarring **Device**	C-SD: Complaints by client in the absence of discernible abnormal scarring/disfigurement.	C-SD: Discernible but re-operation not required. Usually noticed first by the client and reported to the provider.	C-SD: Discernible and requires re-operation or referral/transfer to another facility.
TREATMENT	**FOR SURGERY** • Reassure client that with healing of the wound, the appearance of the penis will improve. **FOR DEVICE** • Management as above for surgery.	**FOR SURGERY** • Reassure client that with healing of the wound, the appearance of the penis will improve. **FOR DEVICE** • Management as above for surgery.	**FOR SURGERY** • **Refer** to a specialist/urologist who may consult a plastic surgeon in cases of severe scarring or disfigurement. **FOR DEVICE** • Management as above for surgery.

TORSION OF PENIS

Defined as: Rotation or twisting of the penis to either side of the midline that can lead to pain or discomfort with erections

Penile torsion is very rare and usually occurs when there is failure to correctly align the frenulum with the median raphe (line of fusion of the two halves of the penile skin along the underside of the penis) during surgery. There is no corresponding line on the dorsal (uppermost) side of the penis. Sometimes torsion is also caused by excess skin removal that is compensated for intra-operatively by moving the remaining skin about.

Some torsion may only be visible at the time of erection or more prominent with an erection, and therefore difficult for the provider to assess when the penis is examined in a flaccid state. Having the client take a photo of his penis when he has an erection (such as upon waking in the morning) can be very helpful in the assessment of torsion or any other erection-related abnormality.

If the torsion or misalignment of tissue is noted while applying the dressings at the end of the surgical procedure, remove all the sutures and start again. If the torsion is corrected, it need not be reported as an AE, however if a single provider needs to correct torsion multiple times, retraining should be considered. With proper surgical technique, this AE should not be seen. Since torsion of the penis noted at the time of surgery should be addressed at that time, torsion of the penis should be classified only as C.

Additional and special considerations for devices
With use of devices, assessment of torsion will be possible only after device removal, and therefore should be classified as C. In theory, since there is not separation and re-alignment of the skin, torsion should not occur with use of devices.

ADVERSE EVENT	MILD	MODERATE	SEVERE
CONSIDER OBTAINING SERIAL PHOTOGRAPHS TO DOCUMENT ADVERSE EVENT AND PROGRESS			
Description: **Torsion of penis** **Surgery**	C-SD: Torsion present but does not cause pain or discomfort.	C-SD: Torsion present that causes mild pain or discomfort with erection but does not require surgery to correct.	C-SD: Torsion present. Erections are painful and client cannot tolerate the appearance, discomfort, or pain. Surgery needed for correction.
Description: **Torsion of penis** **Device**	C-SD: Torsion present but does not cause pain or discomfort.	C-SD: Torsion present that causes mild pain or discomfort with erection but does not require surgery to correct.	C-SD: Torsion present. Erections are painful and client cannot tolerate the appearance, discomfort, or pain. Surgery needed for correction.
TREATMENT	**FOR SURGERY** • Reassure client that cases improve in appearance with re-moulding of the tissue as the penis heals. Even mild pain or discomfort disappears as the skin elongates during healing. **FOR DEVICE** • Management as above for surgery.	**FOR SURGERY** • Reassure client that cases improve in appearance with re-moulding of the tissue as the penis heals. Even mild pain or discomfort disappears as the skin elongates during healing. **FOR DEVICE** • Management as above for surgery.	**FOR SURGERY** • **Refer** to a specialist for potential re-operation. **FOR DEVICE** • Management as above for surgery.

INSUFFICIENT SKIN REMOVAL

Defined as: A state where the skin at the coronal sulcus partially covers the glans when the penis is in a flaccid state.

Newly-trained VMMC providers are often nervous about excising too much foreskin, as this could lead to difficulty with wound closure. This may lead to an overly cautious approach regarding the amount of foreskin removed, with resultant insufficient skin removal and the outcome of a *partial circumcision*. Insufficient skin removal is also seen when there has been failure to fully retract the foreskin at the time of circumcision or device application; this is more likely in younger adolescents where physiological adhesions may be present.

With insufficient skin removal, the glans of the flaccid penis is partially covered by residual foreskin rather than completely exposed.

Ideally, insufficient skin removal should be noted and addressed at the time of initial surgery (time period A), so that correction can be made at that time and re-operation is not required. With the forceps-guided method, insufficient skin removal can be diagnosed based on the presence of a wide margin of inner foreskin remaining, where the shaft skin can easily be stretched to cover the glans or part of it. However, removal of a sleeve of tissue after some or most of the foreskin has been excised requires additional technical skill and should not be attempted by a provider inexperienced in this type of revision, including during revision at the time of the initial surgery. **With proper surgical technique, this AE should not be seen.**

To correctly assess the amount of foreskin excised post-operatively, providers need to observe the penis in a flaccid state once operative swelling has completely subsided and without pulling on the remaining foreskin. Therefore, **a postoperative diagnosis of this AE can only be classified as C with both surgery and devices**.

Clients with insufficient skin excision not noted at the time of the initial procedure often present dissatisfied and complain of a poor cosmetic result. Re-operation may be needed; this decision should include consideration of the fact that remaining foreskin can serve as an entry point for HIV infection and decrease the preventive effect of male circumcision. Re-operation may require a sleeve technique, and should therefore be carried out only by a provider experienced in that technique.

Additional and special considerations for devices
Improper placement can result in insufficient skin removal. As with surgical MC, if insufficient skin removal is not noted until after healing, re-operation may be needed, may require a sleeve technique, and should be carried out only by a provider experienced in that technique.

PrePex

Insufficient skin removal can result from any of several different errors or omissions in device placement.

- Commonly, mild forms of inadequate skin removal can result from marking of the circumcision line too far from the coronal sulcus (i.e., more distal from the sulcus than it should be), either all around the circumference of the penis (symmetrically) or asymmetrically. This leads to incorrect device placement with resultant insufficient skin removal. The insufficient skin removal may often not be noticed until after day 7 when oedema has subsided. Proper skin marking will decrease the risk of insufficient skin removal occurring from incorrect device placement.
    - This may also occur if the ink of the marked line is rubbed off with cleaning. Care is needed with application of topical anaesthesia with PrePex placement: anaesthetic cream should be applied only to the inner surface of the foreskin. Application of cream to the outside of the foreskin can make the skin marking difficult to see or can make the ink wipe off, leading to improper device placement.
- Less commonly, more moderate forms of inadequate skin removal can result from varying degrees of failure to push the inner ring all the way down to the sulcus. If this is noted at the time of placement, the device should be removed and replaced in the proper position.
    - This failure can be symmetrical, or asymmetrical, where the inner ring is unevenly seated in the coronal sulcus, with one side of the ring not lying in the sulcus, leading to an asymmetric circumcision with insufficient skin removal of part of the foreskin.
- Rarely, more severe inadequate skin removal can result from invagination of the foreskin, where part or all of the foreskin becomes folded upon itself with the placement of the inner ring. Invagination is caused by ***failure by the provider to conduct final inspection of the inner ring*** at completion of device placement to visualize the inner ring in situ. This inspection should be included in all placements prior to cutting the verification cord. Making sure there is even tension on both the external and internal surfaces of the foreskin with PrePex placement, ensuring the entire surface of the inner ring can be seen between the foreskin and the glans after placement, and that there are no areas where the surface of the ring is covered by invaginated inner mucosal surface, will prevent this problem. If invagination is recognized immediately, the device should be removed and replaced properly. In cases of severe insufficient skin removal, surgical revision is needed.
- In some cases of insufficient skin removal, the severity of the problem can in determined at the time of device removal and a decision can be made regarding the need for immediate surgical revision. In other cases, the severity of the problem may be difficult to discern due to oedema and/or presence of an eschar and the need for surgical revision should be determined after healing.

ShangRing

- If insufficient skin removal is noted at the time of placement of ShangRing, the device should be removed and there should be surgical correction. As noted above, this may require additional surgical skill and should not be attempted by a provider inexperienced in this type of revision.
- If the ring is not properly placed, insufficient skin removal may result.
- If not noted until after healing, re-operation may be needed and may require a sleeve technique, which should be carried out only by a provider experienced in that technique.

ADVERSE EVENT	MILD	MODERATE	SEVERE
CONSIDER OBTAINING SERIAL PHOTOGRAPHS TO DOCUMENT ADVERSE EVENT AND PROGRESS			
Description: Insufficient skin removal **Surgery**	C-SD: Prepuce extends over the coronal margin but less than one third of the glans is covered in flaccid state.	C-SD: Prepuce partially covers glans when flaccid but surgical correction is not necessary.	C-SD: Prepuce covers most of the glans when flaccid and surgical correction is necessary.
Description: Insufficient skin removal **Device**	C-SD: Prepuce extends over the coronal margin but less than one third of the glans is covered in flaccid state.	C-SD: Prepuce partially covers glans when flaccid but surgical correction is not necessary.	C-SD: Prepuce covers most of the glans when flaccid and surgical correction is necessary.
TREATMENT	**FOR SURGERY** • Reassure the client; no further action needed. **FOR DEVICE** • Management as above for surgery.	**FOR SURGERY** • The foreskin easily retracts and one-third to two-thirds of the glans is covered by the residual prepuce. • The decision to re-operate should be taken in consultation with the client. • **Refer** to experienced MC provider for re-circumcision by sleeve resection in a hospital. **FOR DEVICE** • Management as above for surgery.	**FOR SURGERY** • Greater than two-thirds of the glans is covered by residual prepuce or there is stenosis of the residual aperture preventing foreskin retraction. • The decision to re-operate should be taken in consultation with the client. • **Refer** to experienced MC provider for re-circumcision by sleeve resection in a hospital setting. **FOR DEVICE** • Management as above for surgery.

EXCESS SKIN REMOVAL

Defined as: Removal of too much foreskin, such that there is difficulty in wound closure

Excess skin removal is a difficult and stressful complication to manage. Providers should call for assistance or transfer clients to referral centres as soon as they have concerns or are not comfortable/feel unable to deal with this adverse outcome. Skin loss or large skin defects can lead to scarring and dysfunction, but early referral for skin grafting can decrease the likelihood of these outcomes.

Extreme care should be taken to prevent excess skin removal**. Proper skin marking prior to the procedure is the best means of prevention and should be performed in each circumcision, and providers need to be well trained in this technique.**

Look for:

- Difficulty in approximating the foreskin and mucosal edges during suturing, or inability to approximate the edges.
- Tension on sutures when approximating the shaft skin and mucosal edge.

Additional and special considerations for devices
With devices, excessive skin removal has not yet been reported. It could be possible with improper placement, if the foreskin is stretched too much such that shaft skin is pulled beyond the device and removed with the foreskin (PrePex), or excessive inner foreskin is removed resulting in insufficient tissue cuff to hold the device in place (ShangRing). This should not happen with proper training.

PrePex

- There should be marking of the skin prior to procedure to assure proper placement.
- Excessive skin removal will likely only be detected after device removal, and should be classified as C.

ShangRing

- Skin marking is not used when the foreskin is everted over the device inner ring.
- If there is excessive skin removal, it is theoretically possible that there would not be enough tissue to hold the device properly in place. This has not been reported. However, should it occur, it would be classified as A1 and would be managed as with excessive skin removal encountered with surgery.
- Excessive skin removal will likely only be detected after device removal, and should be classified as C.

INTRA-OPERATIVE EXCESS SKIN REMOVAL

ADVERSE EVENT	MILD	MODERATE	SEVERE
CONSIDER OBTAINING SERIAL PHOTOGRAPHS TO DOCUMENT ADVERSE EVENT AND PROGRESS			
Description: Excess Skin Removal *Intra-operative* Surgery	A-SD: Tightness of skin discernible but additional sutures or mobilisation of skin not needed for skin closure.	A-SD: Tightness of the skin discernible and additional sutures or skin mobilisation needed for wound closure, but no other intervention needed.	A-SD: Provider unable to close skin; referral to another facility required.
Description: Excess Skin Removal *Intra-operative* Device	Not applicable	Not applicable	Not applicable
TREATMENT	• Skin tightness can resolve as skin stretches after surgery. • Follow up as needed to assess wound closure and healing.	• Additional sutures by an experienced operator; if not available, cover wound with a moist dressing and **refer** to a higher-level health care facility and classify as severe. • Regular follow-up to ensure good wound healing and review the integrity of the suture margin. • It may be necessary to review clients 6–12 months post-circumcision after complete wound healing. In most cases, tightness with erections will resolve by this time, but a small number of cases will need referral (severe AE).	• Cover the wound with a moist dressing. • **Refer** to a higher-level health care facility to determine need for skin graft to help close the wound.

POST-OPERATIVE EXCESS SKIN REMOVAL

ADVERSE EVENT	MILD	MODERATE	SEVERE
Description: Excess Skin Removal ***Post-operative*** **Surgery**	B/C-SD: Slight tightening of the skin observed; no surgical correction needed.	B/C-SD: Pulling of scrotal skin onto the penile shaft, wound disruption or disruption of sutures due tension on stitches.	B/C-SD: 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.
Description: Excess Skin Removal ***After removal*** **Device**	C-SD: Slight tightening of the skin observed; no surgical correction needed.	C-SD: Pulling of scrotal skin onto the penile shaft and wound disruption.	C-SD: 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.
TREATMENT	**FOR SURGERY** • Reassure client that most skin tightening and mild pain on erection resolves as skin on the wound stretches. **FOR DEVICE** • Management as above for surgery.	**FOR SURGERY** • May need to remove sutures and allow healing by secondary intention. It may be necessary to review clients 6–12 months post circumcision after complete wound healing. In most cases, tightness with erections will resolve by this time, but a small number of cases will need referral for plastic surgery (severe AE). **FOR DEVICE** • Management as above for surgery.	**FOR SURGERY** • **Refer** to a higher-level health care facility. **FOR DEVICE** • Management as above for surgery.

INJURY TO PENIS

Defined as: Injuries to the penis or complications due to the actions of the provider. Most injuries occur during the surgical procedure and are noted at that time, but sometimes injuries such as bruising are not apparent until later. **Unlike other AEs, these AEs should be classified at the time that they are noted, rather than the time they occur; hence the definition for post-operative injury to penis.**

Injuries to the penis can involve one or a combination of the following:

- Glans: a cut into the glans (laceration), or partial or total severing (amputation)
- Shaft: a cut, laceration or diathermy burn of the skin
- Urethra:
    - Fistula: a tract between the urethra and the skin, usually in the frenular area at the base of the glans, through which urine can leak
        - Immediate damage resulting in leakage of urine within the first few days of circumcision
        - Damage causing tissue necrosis over time, or a stitch through the urethra, causing development of a fistula over time. Wound infection may contribute to this process.
        - Fistulas may be most likely to form in young clients with immature penises, where the urethra lies closer to the surface than in sexually mature penises.
    - Blockage (occlusion) of the urethra resulting in difficulty or inability to pass urine
        - Immediate occlusion from a stitch around the urethra or externally around the glans, or severe swelling compressing the urethra. In the case of a stitch around the urethra, it is also impossible to pass a catheter until the stitch has been removed.
        - Damage to the urethra leading to later development of scar tissue in its wall, causing narrowing (stricture).
- Nerve damage: Severing of branches of the dorsal nerve of the penis caused by too deep a cut when removing the foreskin, and resulting in areas of numbness in the glans. When the sleeve method of circumcision is used, particular care has to be taken not to cut too deeply when making the distal ring incision.

The mechanisms of injury to the penis can include one or more of the following:

- Too deep a cut with a scalpel or scissors when removing the foreskin.
- During the forceps-guided method: partial or total amputation of the glans because of difficulty in identifying the location of the glans, leading to accidentally catching some or all of it between the blades of the guiding forceps.
- During the dorsal slit procedure:
    - Cutting too close to or deep near the base of the frenulum, damaging the urethra or its blood supply.
    - Wrong placement of the 12-o'clock crushing forceps so that the inner blade of the forceps wrongly enters the urethra, rather than the space between the foreskin and the glans

- Wrongly-placed sutures:
    - Taking too deep a “bite” or tying sutures too tightly, thus devitalising areas of tissue
        - This is a particular problem when placing sutures to control bleeding from the frenular artery, and is more likely to happen if the cut to remove the foreskin has been made too close to the base of the frenulum. This can result in the suture catching or encircling the underlying urethra and causing tissue necrosis and urethral fistula, or urethral obstruction.
    - Taking too deep a “bite” with the 6 o’clock closing suture and catching the underlying urethra in the suture. This can occur with all methods of surgical circumcision.
- Wrong diathermy technique
    - Using diathermy too close to the skin edge: this is a common mistake which causes an area of skin necrosis and predisposes to infection. Instead, providers should know that skin edge bleeding usually stops once the circumcision closing sutures have been placed and tied.
    - Prolonged use of diathermy: this causes an area tissue damage and can lead to infection or necrosis. Prolonged use of diathermy in the frenular area can result in necrosis of the urethral wall, causing urethral fistula to develop days or weeks after the circumcision.
    - There are rare reports of complete penile loss following prolonged use of diathermy. This should never happen if diathermy application is accurate, short and not used on infants or when the penis is very small. Also, if there is not immediate visible effect of the diathermy at the tip of the diathermy forceps, the surgeon should stop using diathermy (see text on diathermy in WHO manual).

Management

Prevention is the best management. It is achieved by good training and by providers being familiar with the most likely complications of the procedure that they are using. Providers should be particularly aware of:

- For forceps-guided surgical circumcision:
    - **Forceps-guided circumcision should not be used for clients aged 10-14 years or any clients with immature genitalia or severe adhesions;** other methods that directly visualize the glans (i.e., dorsal slit or sleeve resection) should be used. Forceps-guided VMMC in these clients increases the risk for severe glans damage or amputation. A crucial step in this procedure is palpation of the glans through the foreskin after the forceps has been applied to ensure that no part of the glans is trapped in the forceps before the foreskin is cut is; however, this is unreliable in young clients because of the small size of the glans.
    - This risk of glans injury exists for clients of all ages if the forceps are wrongly placed.
- For dorsal slit circumcision, lacerations of the glans, usually small and minor, can also be seen, as the surgeon uses multiple cuts to remove the prepuce with this method.

- For any method, there is risk of urethral injury when working in the frenular area. Do no cut too close to the base of the frenulum, take care when placing sutures, and do not use diathermy around the frenulum. The 6-oclock mattress suture at the frenulum should be a horizontal (not vertical) mattress suture, and care must be taken not to incorporate deeper layers (see WHO Manual).

In general, if a simple injury occurs at the time of surgery and is recognised then or within a few hours, it should be repaired immediately if a competent provider is available. For example, an accidental cut into the skin of the shaft or glans should be sutured. However, any more extensive injury, such as amputation of the glans or urethral injury including fistulas, should only be managed by an expert surgeon. This is because early, appropriate management is crucial to preventing long-term sequelae. For example, urethral repairs done by inexperienced providers can raise the risk of stricture. Each case has to be judged depending on the extent of the injury and the proximity of expert surgical help, and potentially with the help of telephone advice. It is safer to refer too many rather than too few cases.

In the case of fistula appearing with urine leakage days or weeks after circumcision, surgical repair is very difficult and should only be attempted by a specialist in a referral centre. More often than not, repairs by a non-specialist provider fail and result in further complications such as urethral stricture, the need for multiple operations and a lifelong problem. **In the case of amputation, use of diathermy to control bleeding is discouraged,** because it is not effective in stopping bleeding from erectile tissue and can interfere with reattachment. Pressure should be used instead.

Additional and special considerations for devices

- Injury may happen any time sharp instruments (blade and Harvey wire scissors) are used.
- With devices, electrocautery is not used and burns are not a described AE. Urethral fistulas also have not been noted.
- Because the devices are made of hard plastic and are worn for 7 days, they can cause injury in the event of a blow or trauma to the genital area, such as in a motor/bicycle vehicle accident.
- As with surgery, some injuries may not become apparent immediately. Injuries noted after removal have likely been sustained during removal. Nonetheless, they should be classified as C.

PrePex

- Sharp instruments are not used for placement, so injury during placement is unlikely. At the time of removal of the necrotic foreskin, the glans cannot be well visualized initially. Care must be taken not to injure the glans with the removal scissors.
- Displacement of the device can result in swelling of the penis with formation of bullae. (See displacement section.)
- There have been several cases in which premature sloughing of the foreskin has been observed while PrePex is in place. This is very rare so there is little clinical information to date. In several cases, part of the inner mucosa has separated from the rest of the foreskin, protruding from the end of the foreskin. In a single case, this appeared as a urine filled sac. The appearance is alarming but involves only the necrosing foreskin; vital tissue is not affected. While this is not listed as a defined AE in this guide, it should be reported so that additional data on this rare event can be gathered.

ShangRing

- Injury is possible at the time of placement, during wearing, or at removal. As with surgical circumcision, care should be taken to safely excise the foreskin without injuring the glans or shaft at the time of device placement.

INTRA-OPERATIVE INJURY TO PENIS

ADVERSE EVENT	MILD	MODERATE	SEVERE
CONSIDER OBTAINING SERIAL PHOTOGRAPHS TO DOCUMENT ADVERSE EVENT AND PROGRESS			
Description: **Injury to Penis** ***Intra-operative*** **Surgery**	A-SD: Limited superficial laceration or burn injury not requiring additional dressings.	A-SD: 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.	A-SD: 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.
Description: **Injury to Penis** ***during placement*** **Device**	A1-SD: Limited superficial injury not requiring additional intervention.	A1-SD: Abrasion or small laceration of the glans or shaft requiring pressure dressing, but surgical repair is not required.	A1-SD: Injury that requires surgical intervention to stop bleeding or repair.
TREATMENT	**FOR SURGERY** **Damage caused by scalpel or cautery:** • Attend to any bleeding. If any further attention is required, reclassify. • Ensure the paraffin gauze covers the affected areas with daily dressing changes until complete healing. **FOR DEVICE** • Management as above for surgery.	**FOR SURGERY** **Damage caused by scalpel:** • Attend to any bleeding. • Apply simple sutures if the wound is small with discernible edges not involving the urethra or urethral meatus. **Damage caused by cautery:** • Apply paraffin gauze dressings to small mucosal burns with daily dressing changes until complete healing. **FOR DEVICE** • Management as above for surgery.	**FOR SURGERY** • Severe injuries may require both immediate and later surgery for repair. • In the case of a fistula, the client should be promptly referred for specialist evaluation. Repair should not be attempted by nonspecialists. **Damage caused by scalpel:** • Severe damage should be evident during surgery and should be immediately addressed by a competent provider. • If necessary, bleeding can be controlled by a pressure dressing or wrapping the penis in gauze and sustained manual

ADVERSE EVENT	MILD	MODERATE	SEVERE
			pressure until a competent provider arrives or during transport to a higher level facility. • In the case of amputation, diathermy should be avoided as it is not effective in stopping bleeding from erectile tissue and can make reattachment of the severed glans more difficult. • Severed tissue should be sent with the client. The tissue should be wrapped in sterile gauze, ideally soaked in sterile saline. • **Refer** if necessary for treatment monitoring and evaluation. **Damage caused by cautery:** • **Refer** if necessary for treatment monitoring and evaluation especially for clients sustaining larger burns in the vicinity of the urethra. **FOR DEVICE** • Management as above for surgery.

POST-OPERATIVE INJURY TO PENIS

ADVERSE EVENT	MILD	MODERATE	SEVERE
CONSIDER OBTAINING SERIAL PHOTOGRAPHS TO DOCUMENT ADVERSE EVENT AND PROGRESS			
Description: **Injury to penis** ***Post-operative*** **Surgery**	B/C-SD: Bruising or abrasion, or limited superficial laceration, or burn injury not requiring additional dressings.	B/C-SD: Significant laceration or burn injury requiring either prolonged follow-up care and attention, or repeated or additional dressings, but not requiring surgical correction or hospitalisation.	B/C-SD: 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.
Description: **Injury to penis** ***during wearing, at removal or after removal*** **Device**	A2/B/C-SD: Limited superficial injury not requiring additional intervention.	A1-SD: Bruise, abrasion or small laceration of the glans or shaft requiring pressure dressing, but surgical repair is not required.	A1-SD: 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.
TREATMENT	**FOR SURGERY** • Apply paraffin gauze to affected areas and repeat daily dressing until complete healing.	**FOR SURGERY** **Damage caused by cautery:** • Apply paraffin gauze to affected areas and repeat daily dressing until complete healing. • For burns from cautery, start on	**FOR SURGERY** • Severe AE should have been noted at the time of surgery and referred at that time. However, should there be signs of severe injury in the post-operative period, refer to a specialist.

ADVERSE EVENT	MILD	MODERATE	SEVERE
	FOR DEVICE • Management as above for surgery.	prophylactic treatment with antibiotics, such as amoxicillin/clavulanic acid, or in accordance with national guidance or locally available drugs. • Examine for the presence of a fistula and refer to a specialist for evaluation and repair. • Follow closely for signs of infection. **FOR DEVICE** • Attend to any bleeding. • Apply simple sutures if the wound is small with discernible edges not involving the urethra or urethral meatus.	• Examine for the presence of a fistula and refer to a specialist for evaluation and repair. **FOR DEVICE** • Management as above for surgery.

OTHER ADVERSE EVENTS: EXCESS SWELLING OF PENIS/SCROTUM INCLUDING HAEMATOMA, PROBLEM WITH VOIDING (URINATING), OTHER

This section includes excess swelling of penis/scrotum including haematoma, problem with voiding and any other AEs that have not been described elsewhere in this document.

EXCESS SWELLING OF THE PENIS/SCROTUM INCLUDING HAEMATOMA

Defined as: Accumulation of fluid or blood in the tissue at the site of the wound that may extend to surrounding areas

Haematoma or swelling noted at the time of surgery or device placement, or any other time prior to discharge, is an indication of acute bleeding and should be classified and managed as bleeding, A-BL for surgery or A1-BL for devices.

Some swelling is part of the natural healing process, as are small areas of bruising or haematoma at the edges of a wound. Swelling with haematoma is caused by bleeding that either has resolved or is still ongoing. Swelling or haematoma noted after surgery should be classified as B or C. If it is associated with ongoing external bleeding and/or infection, these AEs should also be reported.

With haematoma:

- Increasing swelling or extension of the haematoma into adjacent tissues indicates ongoing bleeding. Provider should carefully assess whether there is ongoing bleeding, as this may be an indication for exploration of the wound and should be managed as ongoing bleeding.
- The presence of a haematoma may be indicated by a dusky appearance of the skin, indicating underlying blood.
- Haematoma may be more localized whereas swelling from other causes may be more diffuse.
- Haematomas without active bleeding should resolve spontaneously and can be treated conservatively. Even large haematomas are often best managed conservatively, particularly if diagnosed some days after circumcision. When exploration is undertaken, the risk of infection is increased and the time to recovery is no different from conservative management. Resolution may take several weeks.
- If ongoing bleeding is suspected, the wound should be opened, explored, and managed in the same manner as post-operative bleeding.
- A large collection of blood may cause discomfort and need to be evacuated for relief, even if there are no signs of ongoing bleeding.
- Retained blood can increase the risk of infection, so a higher suspicion for infection is needed in these cases and antibiotic therapy might be indicated.
- An algorithm for management of a haematoma is below and included as Appendix 8.

A haematoma with ongoing bleeding should be reported as both haematoma and bleeding and managed as described in the bleeding chapter. An algorithm on the management of haematoma from MC is included in as Appendix 8 and on the following page.

Any haematoma that recurs could indicate a bleeding abnormality, and should be followed closely or referred for further evaluation.

With swelling **not** associated with haematoma:

- Swelling is part of the healing process and should resolve over time.
- Increasing swelling, particularly if painful, can be an indication of a problem such as infection and may be indicated by accompanying drainage from wound, surrounding erythema or warmth.
- Swelling with formation of bullae or blistering should be considered as a sign of a potential serious AE, such as a necrotising or other severe infection, and should be evaluated carefully, especially when accompanied by erythema, fever or other systemic signs.
- If infection is suspected, follow closely and consider starting oral antibiotics (see also instructions under “Infection”).

Additional and special considerations for devices

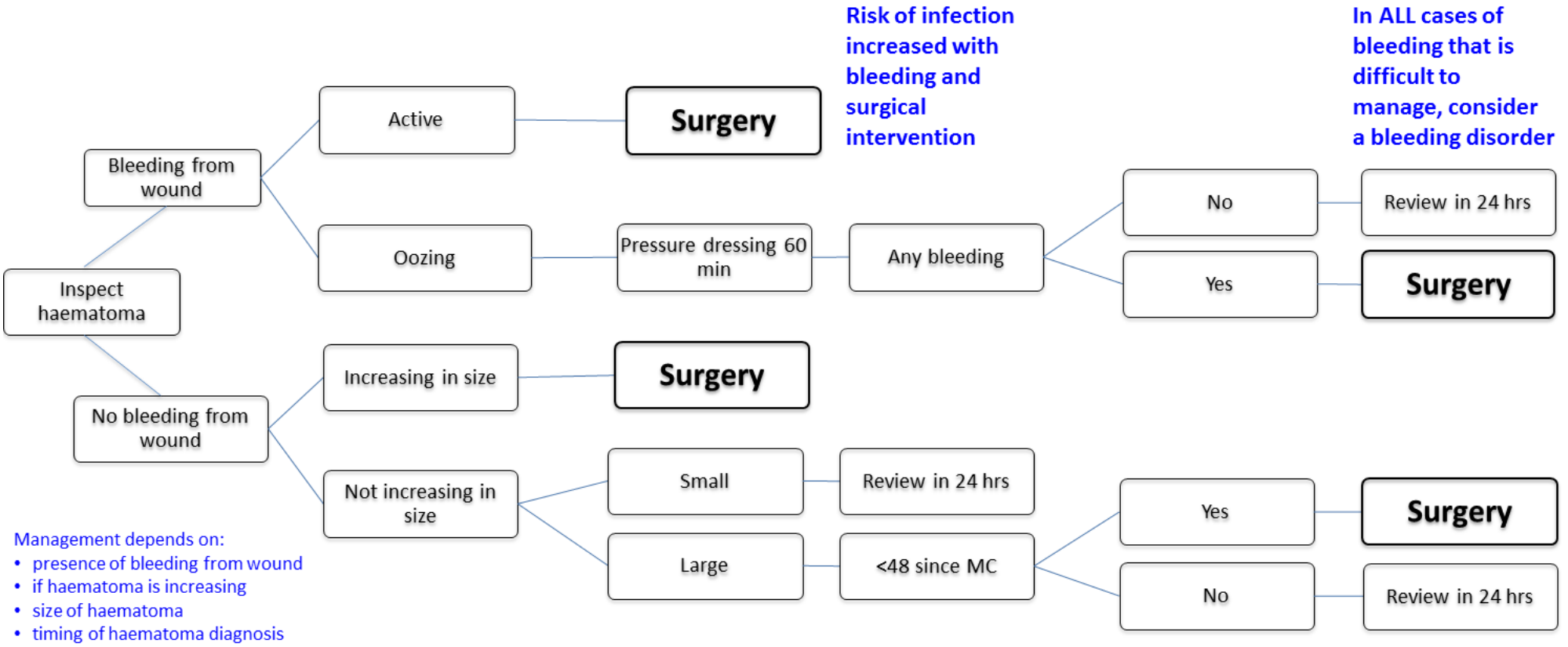
Haematoma and swelling can occur while wearing the device, with self-removal or displacement of the device, or after removal. It would be classified as A2 or C.

PrePex

- Swelling of the foreskin that occurs with device displacement or early removal should be classified as severe and requires prompt attention.
    - Swelling associated with this AE may be significant and accompanied by pain, bullae and loss of skin.
    - Usually a surgical circumcision is needed to prevent serious outcomes.
    - Because of distorted anatomy with excessive swelling, a sleeve technique may be needed for circumcision, and therefore the provider attending the client should be skilled in the technique.
    - **Under no conditions should a forceps-guided technique be used when a surgical circumcision is performed with swelling caused by device displacement**. Because the swelling makes palpation of the glans difficult, it is crucial to be able to visualize the glans to ensure it is not damaged.

Management of penile haematoma after circumcision, MC sites

Surgical exploration by experienced providers only



ADVERSE EVENT	MILD	MODERATE	SEVERE
CONSIDER OBTAINING SERIAL PHOTOGRAPHS TO DOCUMENT ADVERSE EVENT AND PROGRESS			
Description: Excess swelling of penis/scrotum including haematoma **Surgery**	B/C-OA: Mild swelling without signs of ongoing bleeding.	B/C-OA: Symptoms/signs that require clinical intervention, but not surgical exploration.	B/C-OA: Surgical exploration required to control bleeding or remove haematoma 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, device placement or removal.
Description: Excess swelling of penis/scrotum including haematoma *during wearing device or after removal* **Device**	A2/C-OA: Mild swelling without signs of ongoing bleeding.	A2/C-OA: Symptoms/signs that require clinical intervention but not surgical exploration.	A2/C-OA: Surgical exploration required to control bleeding or remove haematoma 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, device placement or removal.
TREATMENT	**FOR SURGERY** • Reassure client that haematoma/swelling will resolve spontaneously with time. • Elevate the penis by strapping it up against the abdominal wall to help the swelling resolve. A period of rest may help the swelling resolve. **FOR DEVICE** • Management as above for surgery. • If PrePex device is still in place, make sure if it has not migrated from its original	**FOR SURGERY** **IF ONGOING BLEEDING IS PRESENT, CLASSIFY AS SEVERE AND MANAGE ACCORDINGLY.** **IF NO BLEEDING PRESENT:** • Look for signs of infection or other causes of swelling and treat accordingly. • Elevate the penis by strapping it up against the abdominal wall to help the swelling resolve. A period of rest may	**FOR SURGERY** **IF ONGOING BLEEDING IS PRESENT: (Increasing size of swelling or swelling with bleeding from the wound):** • Apply pressure manually with gauze swab and maintain for 5 minutes. • Gently remove swab and attempt to identify the origin of the bleed. • If bleeding continues, administer local anaesthesia and an experienced provider should explore the wound. If bleeding vessel is clearly identifiable,

ADVERSE EVENT	MILD	MODERATE	SEVERE
CONSIDER OBTAINING SERIAL PHOTOGRAPHS TO DOCUMENT ADVERSE EVENT AND PROGRESS			
	placement site. If migrated from original site, additionally classify and manage as device displacement.	help the swelling resolve. • Swelling may take up to 3 weeks to resolve. **FOR DEVICE** • Management as above for surgery. • If PrePex device is still in place, make sure if it has not migrated from its original placement site. If migrated from original site, additionally classify and manage as device displacement.	place a suture at that point and tie securely. • If the bleeding vessel is not identifiable, under-run the bleeding area by starting at a dry point and insert continuous sutures which cross the bleeding area, ending with a knot at a dry part of the surface. • Observe the client for at least one hour and re-inspect the dressing. • Give the client the emergency contact details of the provider on call in case bleeding resumes. • Elevate the penis by strapping it up against the abdominal wall to help the swelling resolve. A period of rest may help the swelling resolve. • **FOLLOW UP** initially daily until the clinical team assesses client's progress as satisfactory. **IF NO BLEEDING PRESENT:** • Look for signs of infection or other causes of swelling and treat accordingly. • Elevate the penis by strapping it up against the abdominal wall to help the swelling resolve. A period of rest may help the swelling resolve. **FOR DEVICE** • Management as above for surgery. • If PrePex device is still in place, make sure if it has not migrated from its original placement site. If migrated from original site, additionally classify and manage as device displacement.

PROBLEM WITH VOIDING (URINATING)

Clients have a natural apprehension about passing urine with the freshly operated penis; however, problems with voiding may go beyond this. Problems with voiding occur when the client who tries to pass urine fails to do so or has to strain to initiate or maintain urine flow. The client will complain of one or more of:

- Inability to pass urine despite an urge to do so, after more than 6–8 hours have passed since surgery.
- Passing small amounts of urine on a frequent basis.
- Only managing a trickle following heavy straining.

This AE will be noted post-operatively and therefore should be classified as B/C or A2/C for surgery and devices, respectively.

Causes of inability to void can range from pain and apprehension to inadvertent ligation of the urethra. Common early reasons for problems voiding are insufficient fluid intake or a bandage that is too tight. Determining that the client has had enough to drink and inspecting the bandage and glans to look for impingement or ischaemic changes from an overly tight bandage are important. A bandage is too tight if one cannot insert a finger between the bandage and the skin. (This definition does not apply to a pressure dressing being used to achieve haemostasis). With moderate difficulty voiding, there may be partial obstruction, with the client either needing to make frequent visits to the toilet and passing only small amounts of urine, or straining to pass urine and being left with the sensation that the bladder is not empty.

A deep suture applied across the urethra or an inadvertent wrap of suture around the glans may cause difficulty with urination. If enough time has passed, the suture may be covered by swollen skin and difficult to visualize. In this case, removal of the bandage does not relieve symptoms and fullness in the bladder will be palpable. Difficulty urinating which develops later after the procedure may result from unrecognized laceration of the urethra during surgery, leading to urethral scarring and stricture.

In such cases, upon asking the client to pass urine, the urethra may be palpable (proximal to the blockage, it may fill with urine and bulge as urination is attempted). Catheterization may be necessary**. Use size 10–12 Fr (French Size) for boys under 12 years, and larger sizes (14-18 French) for males aged 12 years onwards.** Inability to pass a small catheter will confirm obstruction. The patient should be evaluated by an expert surgeon capable of diagnosing the cause of obstruction.

Additional and special considerations for devices
In any case of complaints of difficulty with urination when a device is in place, the device should be carefully examined to make sure that it is not causing any obstruction to the urethra or the urine stream.

PrePex

- As the foreskin becomes necrotic, the opening may narrow and cause obstruction, flow diversion or spraying of the urine stream. Complete obstruction has been reported in those with a long foreskin or who are young.
- Displacement of the elastic band from the inner ring can lead to pressure on the shaft that can in turn cause pressure on the urethra, leading to partial urethral obstruction.

ADVERSE EVENT	MILD	MODERATE	SEVERE
Description: Problem with Voiding (Urinating) **Surgery**	B/C-OA: NA	B/C-OA: 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).	B/C-OA: Complete obstruction and/or requires placement of a catheter, referral for treatment, or surgery to correct.
Description: Problem with Voiding (Urinating) ***during wearing device or after removal*** **Device**	A2/C-OA: NA	A2/C-OA: 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).	A1/C-OA: Complete obstruction and/or requires placement of a catheter, referral for treatment or surgery to correct.
TREATMENT		**FOR SURGERY** • A catheter is indicated where the client still cannot pass urine and the urethra or bladder is palpable, or the client has a painful urge to pass urine and is failing to do so and would generally be classified as severe. • However, if a catheter is required for less than 24 hours, providers may wish to classify this as a moderate AE. **FOR DEVICE** • Examine device to make sure it is not causing any obstruction. • With PrePex, obstruction to flow of urine caused by the necrotic foreskin can be relieved by placing a small cut in the foreskin to increase the size of the	**FOR SURGERY** • **Refer** to a specialist facility. • If urethral catheter is not possible and if the transfer is going to be long or problematic and there is sufficient onsite expertise, a suprapubic catheter may need to be inserted. **FOR DEVICE** • Examine device to make sure it is not causing any obstruction. • If above not present, management as above for surgery.

ADVERSE EVENT	MILD	MODERATE	SEVERE
		foreskin opening, or by early device removal. The choice should be based on clinical judgement. As the necrosing foreskin is not sensitive to pain at this point, anaesthesia or analgesia should not be needed. • If above not present, management as above for surgery.	

OTHER: GASTRITIS

NSAIDS taken for postoperative pain relief have the potential to contribute to gastritis, ulcer exacerbation, and even perforation. These abdominal processes should be considered in postoperative clients presenting with severe abdominal pain, particularly in programmes routinely prescribing NSAIDs. Clinicians treating such clients should ask about medications used for postoperative pain.

SEXUAL DIFFICULTIES OR EFFECTS/UNDESIRABLE SENSORY CHANGES

Defined as: Undesirable sensory changes or changes in or difficulty with sexual function

Sensory changes may include complaint of a patch on the penis where sensation is abnormal, different, or absent. The report and the examination results are often subjective and may vary at different time points and with examination by different providers/practitioners. Some clients report loss of sensation; others a different sensation, or over-sensitivity to the extent that the client avoids intercourse. The diagnosis of sexual difficulties or effects is derived from the history given by the client and is very difficult to quantify. Several studies have attempted to measure sensory changes in the glans penis in both circumcised and non-circumcised males. Results have been varied and at times equivocal. It appears that initially at least, an increase in glans sensitivity occurs following circumcision due to the fact that the glans is newly “exposed”. This effect is almost always temporary and resolves with time. As this is a subjective finding and may have been present prior to circumcision, the only means to definitively determine relatedness to circumcision is by taking a sexual history at baseline prior to the procedure.

With regard to a report of undesirable sensory changes, the objective is to define the location and consistency of the undesirable sensory change. It may be helpful to draw a diagram of the penis marking the areas of sensory changes and use the diagram at each visit to determine changes over time.

Premature ejaculation is defined as an inability to delay early ejaculation and can cause significant distress in clients. Glans hypersensitivity may be part of the pathogenesis of this complex disorder. Circumcision may therefore indirectly be associated with premature ejaculation as a result of the heightened sensation. Once again, this will most likely be a temporary effect that will resolve as the glans hypersensitivity decreases. This resolution interval will vary among individuals. Studies consistently show that after circumcision the time to ejaculation is slightly longer when compared with uncircumcised men and therefore men can be reassured that premature ejaculation, common in young men, is unlikely to be made permanently worse by circumcision.

Some reports have suggested that circumcision may contribute to erectile dysfunction. However, the erectile response is a complex neuro-endocrine and vascular event relying on blood vessels and nerves in the pelvis and perineum. A circumcision does not damage these structures and therefore will not cause erectile dysfunction. In the acute setting, pain may be a physical factor inhibiting erections. This is not usually clinically apparent, as males are advised to abstain from intercourse in the acute post-operative period. At times men present for male circumcision because they have sexual dysfunction, in the hope that the procedure may resolve their problem. Taking a sexual history prior to circumcision, including a history of sexual dysfunction, can be helpful in an assessment of client complaints of sexual problems after circumcision.

Sexual complications/undesirable sensory changes cannot be assessed until there is healing and sexual activity has resumed, and therefore all are classified as C for both surgery and devices.

ADVERSE EVENT	MILD	MODERATE	SEVERE
Description: Sexual Effects/ Undesirable sensory changes **Surgery**	C-SX: Occasional inability to have erection or dissatisfaction with sexual performance, no psycho-behavioural consequences.	C-SX: Post-operative changes that consistently impair or preclude sexual function for 3 to 6 months after surgery not present prior to surgery.	C-SX: Post-operative changes that consistently impair or preclude sexual function for greater than 6 months after surgery that were not present prior to surgery.
Description: Sexual Effects/ Undesirable sensory changes **Device**	C-SX: Occasional inability to have erection or dissatisfaction with sexual performance, no psycho-behavioural consequences.	C-SX: Post-operative changes that consistently impair or preclude sexual function for 3 to 6 months after surgery not present prior to surgery.	C-SX: Post-operative changes that consistently impair or preclude sexual function for greater than 6 months after surgery that were not present prior to surgery.
TREATMENT	**FOR SURGERY** • Reassure client and explain that increased sensitivity is common for the first month or two after MC. • Explore with the client the possibility of pre-existing issues (problems pre-dating the procedure). • Where a client reports a patch with abnormal sensation, he should be advised that this problem is likely to reduce with time. **FOR DEVICE** • Management as above for surgery.	**FOR SURGERY** • Reassure client. • Where the client complaints of hypersensitivity causing premature ejaculation, local anaesthetic gels may be helpful. • In all cases where the client complains that penile sensation changes are causing an inability to obtain a firm erection, he should be referred to an expert in the management of male sexual dysfunction. **FOR DEVICE** • Management as above for surgery.	**FOR SURGERY** • **Refer** all cases to a specialist. **FOR DEVICE** • Management as above for surgery.

DEVICE DISPLACEMENT

Defined as: Movement of MC device from original placement site to another place on the penis or movement completely off the penis. Displacements can be inadvertent, or can result from sexual activity with the device in place or from intentional self-removal. The clinical course and management of this AE should be carefully and fully documented.

Inadvertent slippage or displacement of a device can be the result of use of an incorrectly-sized device, provider error with placement (in the case of ShangRing), client manipulation of the device, or trauma to the genital area. To date, displacement has been uncommon and seen only with the PrePex device. By definition, device displacement takes place in the A2 period; consequences, like edema, take place in the C period.

PrePex

- Cases of displacement need to be evaluated by an experienced clinician.
- The signs and symptoms seen with PrePex displacement depend on the degree of ischaemic necrosis present from the device at the time of the displacement.
    - Displacement that occurs within hours of placement likely will have little consequence, as little or no ischaemia is present. In this case, the device can usually be replaced.
        - There should be reassessment to determine the proper size of device, as an incorrect size can be a risk factor for displacement.
        - If it is determined that displacement was from self-removal or because of sexual activity while the device was in place, the device should not be replaced because the risk of recurrent displacement may be high; instead, circumcision should be done through surgery.
    - Likewise, displacement at the end of the period that the device is in place may also be of little clinical consequence, as there is complete ischaemia and necrosis of the tissue by that time and the foreskin can be removed as in routine removal.
    - In the case of displacement in the first several days after placement, partial ischaemia will be present, and presentation can be dramatic. Extensive swelling of the foreskin can be present often accompanied by pain, bullae and loss of skin. These signs and symptoms above may already be present at presentation, or could develop in the hours after device displacement. Regardless, urgent evaluation is necessary, and in most cases prompt surgical circumcision is needed to prevent serious outcomes.
        - If the anatomy is distorted due to extensive swelling, a sleeve technique may be needed, and therefore the surgeon should be skilled in this technique.
        - Because there should be visualization of the glans throughout the procedure, the forceps-guided technique should not be used.
        - There have been several instances where clinicians have chosen to closely observe cases with significant swelling and delay surgery for several days, until swelling has resolved; more outcome data is needed to help define optimal management and timing of surgery.

- If in doubt about management, the conservative approach is to perform a surgical circumcision soon after the client presents with device displacement.

ShangRing

- Slippage occurs most frequently immediately after excision of the foreskin. Because control of bleeding will be needed, surgical circumcision by an experienced provider should performed.
- Because the force on the tissue by ShangRing is greater than by PrePex, ShangRing is less likely to displace. Displacement is possible, however, with trauma or in other contexts where there is a significant pulling force on the device.
- If slippage or displacement occurs during the first few days after placement, surgery may be needed for haemostasis and wound closure. If it occurs late in the period during which the device is worn, no additional procedure may be needed, as there may be adequate haemostasis and formation of an eschar on the underlying tissue.

ADVERSE EVENT	MILD	MODERATE	SEVERE
CONSIDER OBTAINING SERIAL PHOTOGRAPHS TO DOCUMENT ADVERSE EVENT AND PROGRESS			
Description: Device displacement	A2-DD: NA	A2-DD: Displacement of the device, including intentional movement of device by the client and/or self-removal, that does not require surgical intervention to correct, because the device can be removed, repositioned, or replaced with a new device.	A2-DD: 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.
TREATMENT		For PrePex: • If displacement is in within several hours of device placement, consider repositioning or replacement of device. • If displacement occurs near the day of removal (day 5 or 6), removal of necrotic foreskin and device may be all that is needed. • If device is to be removed and not replaced, and there is not a surgical circumcision, close follow-up is needed to make sure that serious signs and symptoms such as pain, swelling and bullae do not develop. For ShangRing: • For slippage immediately or soon after placement and excision of the foreskin, surgery is needed to complete the circumcision, establish haemostasis and close the wound. • For slippage or displacement later when there is adequate haemostasis and formation of an eschar, complete removal of the device may be the only management needed. • If device is removed early and there is not a surgical circumcision or wound closure, close follow-up is needed to make sure bleeding and wound dehiscence do not develop.	For PrePex and ShangRing: • Surgical circumcision by a provider experienced in sleeve or dorsal slit technique and performing surgery in cases where anatomic landmarks may be distorted. The forceps-guided technique should not be used. • In cases where bullae or sloughing of the skin is present, consider treatment with systemic antibiotics. • Close follow-up either through admission or daily outpatient visits until swelling and bullae subside.

ANAESTHESIA-RELATED EVENTS

SYSTEMIC TOXICITY FROM LOCAL ANAESTHESIA

This is very rare and may occur with unintended intravascular administration or with administration of an excessive dose of anaesthetic**. This is one of the most serious AEs, is difficult to treat successfully, and it is essential to prevent through the following measures:**

- Ensuring correct dosing of anaesthetic agents is the most important measure to prevent anaesthetic toxicity.
    - Know the toxic dose of the local anaesthetics being used and use the lowest effective dose. Doses are weight-based and differ for different sized individuals.
    - Err on the side of lower doses, as additional anaesthetic can administered if needed.
    - Have a clearly-articulated programme policy on standardized anaesthetic dosage.
    - Have posted standardized anaesthetic dosing charts in operating theatres. Double-check doses of local anaesthetics before administration and make sure they are appropriate based on client weight.
    - Double-check concentrations of local anaesthetics before administration - both lignocaine and bupivacaine come in at least two concentrations.
- Use safe injection techniques.
- **ALWAYS aspirate before EVERY injection of an anaesthetic agent** in order to make sure the needle is not in a vessel or the corpus cavernosum.
- Describe early symptoms of local anaesthetic overdose (e.g., metallic taste in the mouth, numbness, light-headedness, dizziness, itching, or shortness of breath) to clients and instruct them to inform you immediately if they experience any effects.
- Maintain verbal contact with the client during the procedure to detect symptoms such as difficulty speaking or confusion.

Lignocaine (lidocaine) is an amide local anaesthetic. Lignocaine with Epinephrine (Adrenaline) is **absolutely contraindicated for use in the penis** because the epinephrine may cause constriction of blood vessels and compromise blood flow to tissues with end-arterial blood supply such as the penis. In some programmes, a mixture of bupivacaine (Marcaine) and lignocaine is used for local anaesthesia, because the mixture provides a longer duration of anaesthesia than lignocaine alone. The mechanism of action and toxicity of bupivacaine are the same as those of lignocaine.

The symptoms of anaesthetic toxicity affect the central nervous and cardiovascular system and tend to follow a predictable progression: Toxicity begins with numbness of the tongue and mouth, light-headedness, and visual and speech disturbances and progresses to muscle twitching, unconsciousness, seizures, respiratory arrest, and cardiovascular depression. Seizures generally will not occur with serum lignocaine levels of less than 10 mcg/ml. If oxygenation, ventilation, and cardiac output are maintained, there can be full recovery without sequelae. However, if serious central nervous system or cardiac complications develop, these can be very difficult to treat, and may require care in an intensive care unit. There is a risk of serious complications, or even death.

DEVICE
With some devices, topical rather than injected local anaesthesia is used at the time of placement and/or at the time of removal. Systemic reactions to topical anaesthetics are extremely rare, and have been reported only when the product is used over large areas of skin such as over both legs, or used on skin that is abraded. These conditions would not be expected with circumcision. Local reactions may include swelling and itching at the site of administration. AEs associated with use of local or topical anaesthetic at the time of placement should be classified as A1, and those associated with use at the time of removal should be classified as B. If systemic signs and symptoms develop, a cause other than topical anaesthetic should be sought. This AE occurs only during surgery or device placement and should be classified as A, A1 or B for surgery and device, respectively.

LOCAL INJECTED ANAESTHETIC DOSING

With regard to local anaesthetic agents, safety needs to be assured at multiple points—from the supply of products to appropriate dosing with proper injection technique and monitoring of the client—including:

- Steady supply of good-quality product so that potency is assured.
- Standardization of anaesthetic agents used; some programmes opt for use of lignocaine alone, while others use lignocaine and bupivacaine because the combination results in rapid onset of action (lignocaine) and longer duration of anaesthetic effect (bupivacaine effect lasts up to 4-5 hours after injection). However, bupivacaine is more expensive than lignocaine.
- Standardization of the concentration of anaesthetic agents used; two commonly used concentrations of lignocaine (1.0% and 2.0%) and bupivacaine (0.25% and 0.5%) are available, and there is an increased potential for dosing errors if concentrations are interchanged.
- Standardization of the ratio of volumes of anaesthetic agents used; the simplest and most commonly used ratio is 1:1.
- Standardization of the amount of anaesthetic used; weight-based dosing is optimal, especially for lower weight clients; some programmes find that above a certain weight cut-off (such as 40 kg) a fixed dose provides adequate pain control for all clients.
- Standardization of the mixing process of the combination of anaesthetic agents.
- Use as small a syringe as possible for dosing the local anaesthetic. Drawing small volumes of fluid into large syringes is may result in measurement errors and more precise measurement of volume is possible in a smaller syringe. For example, with a total volume of 4 ml, it may be best to use 5 ml syringe; for a total volume of 8 ml, a 10 ml syringe may be the best size to use.
- Waiting an adequate time for the effect of the anaesthetic agent(s) to occur; if after an adequate period, pain control is not achieved, additional anaesthetic not to exceed maximum dose can be administered.

The maximum recommended dose is 3.0 mg/kg for lignocaine and 1.5 mg/kg for bupivacaine **when either agent is used alone**. Adequate anaesthesia can be achieved with lower doses and when the two agents are combined, such that the maximum recommended dose is 2.0 mg/kg of lignocaine and 0.5 mg/kg of bupivacaine (Table 1). To aid with calculation of weight-based dosing, milligrams per millilitre for different concentrations of both lignocaine and bupivicaine are listed in Table 2 and dosing charts are included in Appendix 5.

Volumes of maximum doses for heavier clients, particularly when using the lower concentrations of either anaesthetic, may be too large to easily administer into the relatively small anatomic space of the base of the penis. With slow instillation, injection of larger volumes may be possible. Although the recommended dosing charts have been designed to limit starting and maximum dose volumes based on standard syringe sizes, some programmes have found that all clients weighing more than 40 kg may experience adequate pain control with the use of the 40 kg dose/volume. For instance, a client weighing 70 kg may achieve adequate pain control with a dose/volume for a 40 kg client, even though a higher maximum dose/volume may be allowed. This is because the area of tissue that needs to be anaesthetized for circumcision is limited. With use of 2.0% lignocaine and 0.5% bupivacaine in a 1:1 mixture, a volume over 10 ml may not be needed in those weighing over 50 kg. Use of dorsal nerve block (with or without a ring block) may result in a quicker effect and require less volume of anaesthetic.

While safety is paramount, inadequate pain control should also not occur in the context of surgical MC. Pain during the procedure despite use of local anaesthetic should indicate a problem with medications, dose or administration technique, and should signal a need to review medications used, dosing or provider training.

Table 1: Recommended Starting and Maximum Doses for Anaesthetic Agents

Agent	Starting dose	Maximum dose
Lignocaine	2.0 mg/kg	3.0 mg/kg
Lignocaine-bupivacaine combined	1.5 mg/kg-0.3 mg/kg	2.0 mg/kg-0.5 mg/kg

Table 2: Milligrams per Millilitre of Local Anaesthetic

Agent	mg/ml
Lignocaine 1.0%	10 mg/ml
Lignocaine 2.0%	20 mg/ml
Bupivacaine 0.25%	2.5 mg/ml
Bupivacaine 0.5%	5.0 mg/ml

The anaesthetic dosing chart on the following page has been edited from its original version by adding suggested starting doses and maximum doses. For heavier weights, the maximum dose is capped at one that can be delivered in 20 ml as injection of more than this amount of fluid may prove difficult.

Starting and Maximum Doses of 1.0% Lignocaine with and without Bupivacaine, by Volume
If bupivacaine to be used with lignocaine 1.0%, use concentration of 0.25% with 1:1 combination

Safe local anaesthetic dosing—starting* and *maximum*** volumes **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*.		

Safe local anaesthetic dosing—starting* and *maximum*** volumes

Mixture of 1% Lidocaine and 0.25% Bupivicaine

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/bupivicaine 0.3 mg/kg

***Maximum safe dose lidocaine 2.0 mg/kg/bupivicaine 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.

Starting and Maximum Doses of 2.0% Lignocaine with and without Bupivacaine, by Volume
If bupivacaine to be used with lignocaine 2.0%, use concentration of 0.5% with 1:1 combination

Safe local anaesthetic dosing—starting* and *maximum*** volumes

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 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*.

Safe local anaesthetic dosing—starting* and *maximum*** volumes

Mixture of 2% Lidocaine and 0.5% Bupivicaine

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 / bupivicaine 0.3 mg/kg

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

***Use 5ml 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*.

ADVERSE EVENT	MILD	MODERATE	SEVERE
Description: Anaesthesia-related event **Surgery**	A-AN: Mild localised allergic reaction at injection site without swelling and systemic reaction.	A-AN: Reaction to anaesthetic including light-headedness, nervousness, and dizziness that resolves spontaneously over a relatively short period of time and **not** requiring use of medicines or equipment from the emergency cart/kit/list of emergency commodities at VMMC site and no transfer to another facility or admission to hospital.	A-AN: Symptoms of severe systemic allergic reaction to local anaesthetic including rash, urticaria, angioedema, and shortness of breath; or symptoms of overdose of local anaesthetic 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.
Description: Anaesthesia-related event **Device**	A-AN: Mild localised allergic reaction at injection site without swelling and systemic reaction.	A-AN: Reaction to anaesthetic including light-headedness, nervousness, and dizziness that resolves spontaneously over a relatively short period of time and **not** requiring use of medicines or equipment from the emergency cart/kit/list of emergency commodities at VMMC site and no transfer to another facility or admission to hospital.	A-AN: Symptoms of severe systemic allergic reaction to local anaesthetic including rash, urticaria, angioedema, and shortness of breath; or symptoms of overdose of local anaesthetic 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.
TREATMENT	**FOR SURGERY** • Stop the injection immediately and prepare to treat the reaction. **FOR DEVICE** • Wipe off any remaining topical anaesthetic if this was used.	**FOR SURGERY** • Stop the injection immediately and prepare to treat the reaction. **FOR DEVICE** • Wipe off any remaining topical anaesthetic if this was used.	**FOR SURGERY** • Stop the injection immediately and prepare to treat the reaction. • Obtain adequate intravenous access. • Establish control of the airway and ensure adequate oxygenation. • **Refer as soon as possible, keeping**

ADVERSE EVENT	MILD	MODERATE	SEVERE
		• Management as above for surgery. • Look for other cause of signs and symptoms.	**cardiopulmonary functions stable.** **FOR DEVICE** • Wipe off any remaining topical anaesthetic if this was used. • Management as above for surgery. • Look for other cause of signs and symptoms.

EMERGENCY MANAGEMENT

Emergencies are extremely rare events with male circumcision. Despite this, all sites providing VMMC services should be able to handle emergencies. Even sites providing only device services that do not involve injecting local anaesthetic may experience some of the emergency types discussed below. Preparedness includes having emergency management supplies at the site, training providers in emergency management, and having a pre-existing plan for referral of clients. The emergency management plan should include pre-identified sites to which clients with emergencies will be transferred, with current and correct telephone numbers so that in the event of a transfer, the site can be made aware of the transfer and be prepared. Sites should keep on site algorithms for emergency management and should consider posting them in operating theatres. There should also be a protocol for periodic checking of emergency medicines and supplies to make sure all required equipment is in place, in good working order and that no medications are expired. A list of supplies required or highly recommended for PEPFAR-supported sites is included as Appendix 9.

WHO has a number of guides for emergency management that may be helpful, including:

- Best practice safety protocols, including Emergency Resuscitation, Airway Management, HIV Prevention Protocols, Transportation of Critically Ill Patients: http://www.who.int/surgery/publications/immesc_best_practice/en/
- Resuscitation and preparation for anaesthesia and surgery: http://www.who.int/surgery/publications/s16025e.pdf?ua=1
- Generic essential emergency equipment and infrastructure/supplies for emergency and essential surgical care: http://www.who.int/surgery/publications/s15982e.pdf?ua=1

Several situations are mentioned in this section, including anaphylaxis, vasovagal reactions and hypoglycaemia. Vasovagal reactions and hypoglycaemia need to be recognized and not confused with anaphylaxis, as their management is different, and if treated appropriately they are not life-threatening. Reviewing this text should not substitute for emergency training.

ANAPHYLAXIS TO LOCAL ANAESTHETIC AGENTS

This is extremely rare and should not be confused with overdose of local anaesthetic. It may occur in response to the anaesthetic agent or the preservative. Anaphylaxis is likely when all of the following three criteria are met:

- Sudden onset and rapid progression of symptoms
- Life-threatening airway and/or breathing and/or circulation problems
- Skin and/or mucosal changes (flushing, urticaria, angioedema)

Treatment: Follow **A**irway-**B**reathing-**C**irculation (ABC) approach to resuscitate the client.

Note: Adrenaline (epinephrine) is the most important drug for the treatment of an anaphylactic reaction (see dosages below). Adrenaline must be readily available in clinical areas where an anaphylactic reaction could occur. **The intramuscular (IM) route is the best way to administer adrenaline to treat an anaphylactic reaction.** Monitor the client by checking pulse, blood pressure, and electrocardiogram and pulse oximetry, if available. Hydrocortisone is also used in the treatment of anaphylaxis; **however, this drug is an adjunct to adrenaline and not a substitute for it.** The onset of action of adrenaline is immediate, whereas the effect of hydrocortisone is not. Regardless of whether the client seems to improve after treatment, he requires transfer to a facility equipped to care for anaphylaxis, as relapse after several hours is possible

VASOVAGAL REACTION

This is a common effect seen during minor surgery under local anaesthetic or with other minor procedure such as obtaining a venous blood sample. It is not due to anaesthetic toxicity or allergy. Signs and symptoms are generally:

- Light-headedness/dizziness/fainting
- Nausea and vomiting
- Heart palpitations

These signs and symptoms are generally reported during or soon after the operation, and are self-limited and resolve. Treatment consists of laying the client down, elevation of legs, reassurance, close observation, and on occasion, oxygen may be required until clients recover. Vasovagal reactions should not be mistaken for toxicity to anaesthetic agents.

HYPOGLYCAEMIC REACTION

Hypoglycaemia or low blood sugar may be seen in some clients, especially if there are long waiting times for services and if they have not eaten before arrival to the VMMC site. Symptoms of hypoglycaemia can include shakiness, dizziness, sweating, and feeling faint and can mimic a vasovagal reaction. Severe hypoglycaemia can result in confusion or loss of consciousness. As with vasovagal reactions, the client should be placed in a prone position. If a glucometer (a device to measure blood sugar) is available, a blood glucose level can be measured. If the blood glucose level is documented or suspected to be low, the client should be immediately given food or drink that contains sugar. If the client is not capable of eating or drinking because of confusion or loss of consciousness, glucose-containing intravenous fluid can be administered. Once a normal blood glucose level is restored, symptoms should resolve. If not, hypoglycaemia is not the cause of the symptoms and another cause should be sought.

OCCUPATIONAL EXPOSURE

While not an emergency in the sense of needing to perform resuscitation, occupational exposure, for example from a needle stick injury, is an important risk to the provider and needs to be addressed promptly and correctly. Management of these AEs are not covered in this document. ***National guidelines should always be followed and align with the Joint WH/ILO Post Exposure Prophylaxis to Prevent HIV Infection Guidance.*** (http://www.who.int/hiv/pub/prophylaxis/02.pdf)

Instances of occupational exposure need to be reported and monitored to ensure that post-exposure management was appropriate. Also, instances where a provider has more than one occupational exposure may need to be investigated and may trigger a need for retraining on surgical technique or identification of faulty instruments.

SAFE INJECTION TECHNIQUE

PREVENTING INJECTION-RELATED INFECTIONS

While the majority of local anaesthetic injections are performed safely, with little or no risk of infection, transmission of infections to clients or providers is possible if injections are not done safely. There are two types of infections which can be transmitted, both resulting from contamination of an injection needle:

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

In both cases, if the contaminated needle or syringe is 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 types of pathogens have been transmitted in this way, and outbreaks of bacterial and viral infections have been documented. Providers may be tempted to change the needle but re-use 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 he or she is stuck by the hollow injection needle.

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

- **Never** enter a medication vial with a previously-used syringe or needle ("double dipping").
    - If a patient needs additional anaesthesia during a procedure, use **a new needle and syringe** to draw anaesthetic and re-inject. This carries a very small increased cost, but the risks of re-use are much more significant.
- **Never** administer medications from the same syringe to more than one patient, even if the needle is changed or you are injecting through an intervening length of IV tubing.
- **Best practice is to ensure lignocaine vials are not re-used,** by disposing of them during cleanup after each MC. If a provider uses a previously-used anaesthetic vial for a client, it is impossible to know whether the vial is contaminated, for example by a prior provider who incorrectly "double-dipped" into that vial. Outbreaks of bacterial infections have been associated with use of multi-dose vials of medications, including anaesthetics.
    - If it is impossible to eliminate lignocaine vial re-use, the patient's only line of defense is to ensure no provider ever 'double-dips' into a vial. This can prevent transmission of bloodborne pathogens, though bacterial infection can still be transmitted.
- Ensure an adequate supply of extra needles and syringes for anaesthesia that can be accessed without opening an entire MC kit.

Needle stick injuries are a risk for staff. To prevent these injuries:

- **Never** recap used needles two-handed, or use fingers to pick up a suture needle exposed to blood.
- **Always** dispose of used sharp instruments in sharps containers immediately after use.
- Ensure sharps containers are available at every procedure station and not overfilled.

More information is also available from CDC (http://www.cdc.gov/injectionsafety/providers/provider_faqs.html) and the World Health Organization Safe Injection Global Network campaign (SIGN) campaign (http://www.who.int/medical_devices/collaborations/network/en/)

SECTION 4-APPENDICES

This appendix contains the algorithms, tables and figures contained and referred to in this guide. These materials may be of use to aid providers, for example with anaesthetic dosing or management of bleeding. Programmes may wish to use this material as is, or to adapt as appropriate.

Appendices include:

1. Adverse event recording and reporting chart
2. Adverse event timing
3. Adverse event classification and definitions: during surgery, during device placement or prior to discharge from VMMC clinic
4. Adverse event classification and definitions: post-operative period after discharge from VMMC clinic or during device wearing, during device removal or after device removal
5. Anaesthetic dosing
6. Algorithm for prevention and management of acute bleeding after MC
7. Algorithm for management of bleeding after MC by non-MC providers
8. Algorithm for management of penile haematoma after circumcision at VMMC sites
9. VMMC emergency medical supplies, equipment and medicines

APPENDIX 1: ADVERSE EVENT RECORDING AND REPORTING

All AEs should be reported, even if they share a related cause. For example, wound disruption that is caused by an infection should be reported as two AEs: infection and wound disruption. All AEs must be recorded and include time, type, and severity.

MOST COMMON TYPES OF AEs RELATED TO MC, NOT INCLUDING PAIN:

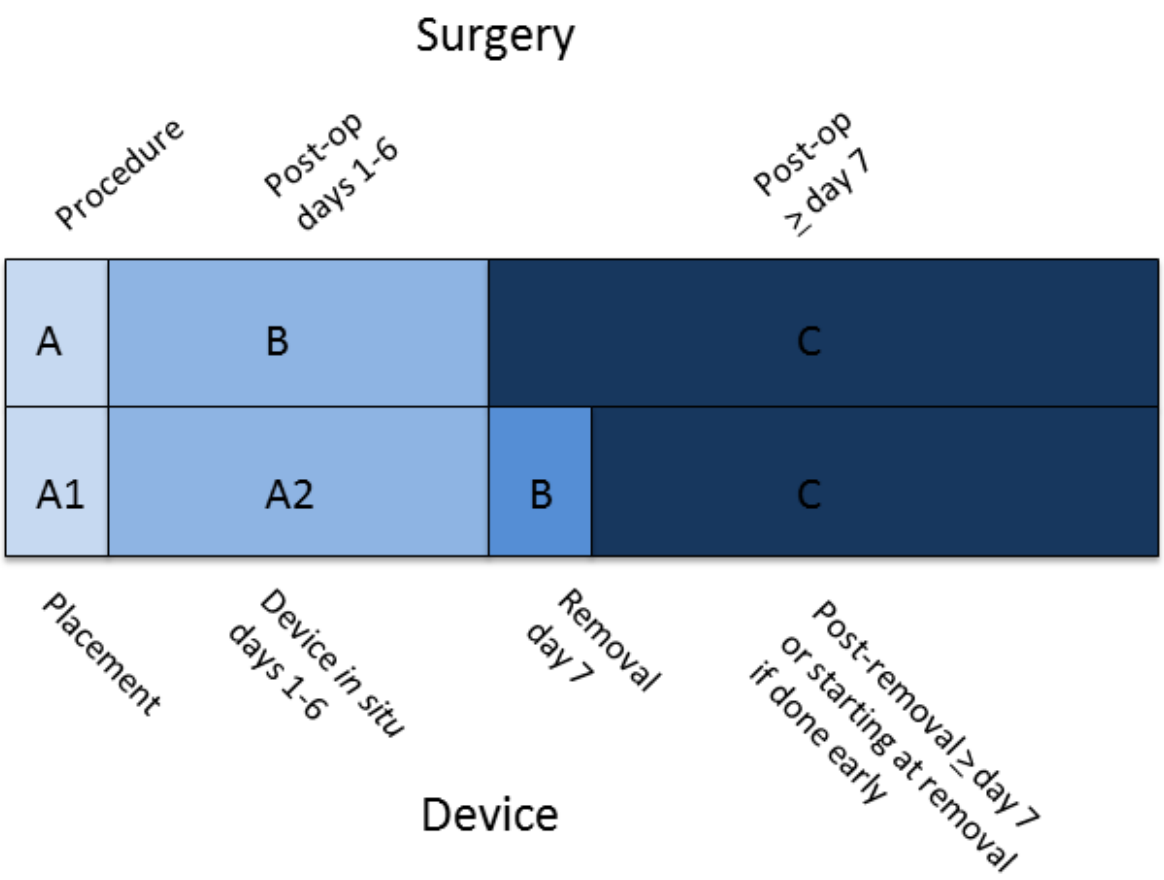
Bleeding related:	**Infection related:**	
• Excessive bleeding • Haematoma	• Infection • Wound disruption	• Abscess formation • Scarring/disfigurement from infection
Bleeding and infection cause over 95% of non-pain AEs reported.		

Time	Type	Severity
FOR SURGERY A = intra-operative (during surgery or prior to discharge from clinic) B = post-operative (1-6 days after surgery and discharge from clinic) C = post-operative (≥7 days after surgery and discharge from clinic) **FOR DEVICE** A1 = during device placement A2 = during week after device placement while wearing device B = during device removal C = after device removal	**AN** = Problem with **An**aesthesia **BL** = Excessive **Bl**eeding **DD** = **D**evice **D**isplacement* **IN** = **In**fection **OT** = **O**ccupa**t**ional Exposure **PA** = **Pa**in **SD** = **S**carring/**D**isfigurement/Poor Cosmetic Result; Insufficient Skin Removal; Excess Skin Removal; Penile Torsion; Injury to Glans or Shaft of Penis **SX** = **Sex**ual Dysfunction/Undesirable Sensory Changes **WD** = **W**ound **D**isruption **OA** = **O**ther **A**Es (Including Excess Swelling of Penis/Scrotum, Haematoma, Difficulty Urinating, Other) *DD is only for devices	Mild Moderate Severe

Example of Coding: An AE coded **A-PA-Moderate** indicates moderate pain during the procedure: **A** = during procedure, **PA** = pain, **moderate**.

The following chart may aid in determining AE timing and can be displayed in clinics.

APPENDIX 2: ADVERSE EVENT TIMING



APPENDIX 3: 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: Anaesthetic-related problem			
Surgery (A-AN) and Device (A1-AN)	Mild localised allergic reaction at injection site without swelling and systemic reaction.	Reaction to anaesthetic including light-headedness, nervousness, dizziness that resolves spontaneously and **not** requiring use of medicines or equipment from the emergency cart/kit/list of emergency commodities at VMMC site and no transfer to another facility or admission to hospital.	Symptoms of severe systemic allergic reaction to local anaesthetic including rash, urticaria, angioedema, and shortness of breath, or symptoms of overdose of local anaesthetic 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	A-BL: Intra-operative bleeding that is more significant than usual or post-operative spotting of the bandage with blood; both easily controlled.	A-BL: 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.	A-BL: 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	A1/A2-BL: Bleeding during placement or wearing that is more significant than usual or spotting of the bandage or clothing with blood; both easily controlled.	A1/A2-BL: Bleeding during placement or wearing that requires a pressure dressing to control without surgical re-exploration of the wound or removal of the device.	A1/A2-BL: 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	A-PA: Client expresses discomfort, however is able to remain still and cooperate for the procedure. No additional local anaesthetic is required.	A-PA: Pain requiring additional local anaesthesia.	A-PA: Pain not responsive to additional local anaesthesia.
Device	A1-PA: Client expresses discomfort, however is able to remain still and cooperate for the procedure.	A1-PA: Client expresses discomfort and is not able to cooperate well with procedure.	A1-PA: Client rates pain as very severe.
SD: Scarring/disfigurement/poor cosmetic result; excess skin removal; injury to penis			
Surgery	A-SD: *Excess skin removal*–tightness of skin discernible but additional sutures or mobilisation of skin not needed for skin closure. A-SD: *Injury to penis*–limited superficial laceration or burn injury not requiring additional dressings.	A-SD: *Excess skin removal*–tightness of the skin discernible and additional sutures or skin mobilisation needed for wound closure, but no other intervention needed. A-SD: *Injury to penis*–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.	A-SD: *Excess skin removal*–provider unable to close wound; referral to another facility required. A-SD: *Injury to penis*–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.
Device	*Excess skin removal*–NA A1-SD: *Injury to penis*–limited superficial injury not requiring additional intervention.	*Excess skin removal*–NA A1-SD: *Injury to penis*–abrasion or small laceration of the glans or shaft requiring pressure dressing, but surgical repair is not required.	*Excess skin removal*–NA A1-SD: *Injury to penis*–injury that requires surgical intervention to stop bleeding or repair.

APPENDIX 4: 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	B/C-BL: 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.	B/C-BL: 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.	B/C-BL: Bleeding that requires surgical re-exploration, hospitalization, or transfer to another facility; or any case where blood transfusion or intravenous fluid is necessary.
Device	B/C-BL: Small amount of bleeding from wound with no active bleeding and is controllable with new dressings or 5–10 minutes of manual pressure.	B/C-BL: 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.	B/C-BL: 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	A2-DD: NA	A2-DD: 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.	A2-DD: 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.

ADVERSE EVENT	MILD	MODERATE	SEVERE
IN: Infection			
Surgery (B/C-IN) **and** **Device (A2/C-IN)**	B/C-IN: Erythema or traces of serous discharge or infective process noted at wound margin. No intervention other than improved wound hygiene.	B/C-IN: Discharge from the wound, painful swelling with erythema, or elevated temperature that requires use of oral antibiotics.	B/C-IN: Cellulitis or abscess of the wound, or infection severe enough to require surgical intervention, hospitalization, or intravenous or intramuscular antibiotics.
PA: Pain			
Surgery	B/C-PA: Client complaints of pain, not requiring more than standard post-operative analgesics and considered within normal thresholds associated with surgery.	B/C-PA: 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.	B/C-PA: 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**.**
Device	A2/B/C-PA: Client complaints of pain, not requiring more than standard post-operative analgesics and considered within normal thresholds associated with surgery	A2/B/C-PA: 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 programmes that utilize a visual analogue scale (VAS) for rating severity, a VAS score of 5–7 (on a 1–10 scale).	A2/B/C-PA: 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 programmes 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; torsion; insufficient skin removal; excess skin removal; injury to penis			
Scarring/disfigurement/ poor cosmetic result; excess skin removal **Surgery (C-SD)** **and** **Device (C-SD)**	*Scarring*-complaints by client in the absence of discernible abnormal scarring/disfigurement. *Torsion of penis*–torsion present but does not cause pain or discomfort.	*Scarring*-Discernible but re-operation not required. Usually noticed first by the client and reported to the provider. *Torsion of penis*–torsion present that causes mild pain or discomfort with erection but does not require surgery to correct.	*Scarring* -Discernible and requires re-operation or referral/transfer to another facility. *Torsion of penis*–torsion present. Erections are painful and client cannot tolerate the appearance, discomfort, or pain. Surgery needed for correction.

ADVERSE EVENT	MILD	MODERATE	SEVERE
	Insufficient skin removal–prepuce extends over the coronal margin but less than one third of the glans is covered in flaccid state.	*Insufficient skin removal*–prepuce partially covers glans when flaccid but surgical correction is not necessary.	*Insufficient skin removal*– prepuce covers most of the glans when flaccid and surgical correction is necessary.
Injury to penis Surgery	B/C-SD: *Injury to penis*-bruising or abrasion, or limited superficial laceration, or burn injury not requiring additional dressings.	B/C-SD: *Injury to penis*-significant laceration or burn injury requiring either prolonged follow-up care and attention, or repeated or additional dressings, but not requiring surgical correction or hospitalisation.	B/C-SD: *Injury to penis*-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.
Injury to penis Device	A2/B/C-SD: *Injury to penis*-limited superficial injury not requiring additional intervention.	A1-SD: *Injury to penis*-bruise or abrasion of the glans or shaft requiring pressure dressing, but surgical repair is not required.	A1-SD: *Injury to penis*-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	B/C-SD: *Excess skin removal*-slight tightening of the skin observed; no surgical correction needed.	B/C-SD: *Excess skin removal*-pulling of scrotal skin onto the penile shaft, wound disruption or disruption of sutures due tension on stitches.	B/C-SD: *Excess skin removal*-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.

ADVERSE EVENT	MILD	MODERATE	SEVERE
Excess skin removal **Device**	C-SD: *Excess skin removal*-slight tightening of the skin observed; no surgical correction needed.	C-SD: *Excess skin removal*-pulling of scrotal skin onto the penile shaft and wound disruption.	C-SD: *Excess skin removal*-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 (C-SX) **and** **Device (C-SX)**	C-SX: Occasional inability to have erection or dissatisfaction with sexual performance, no psycho-behavioural consequences.	C-SX: Post-operative changes that consistently impair or preclude sexual function for 3 to 6 months after surgery not present prior to surgery.	C-SX: Post-operative changes that consistently impair or preclude sexual function for greater than 6 months after surgery that were not present prior to surgery.
WD: Wound disruption			
Surgery	B/C-WD: Wound disruption but not extensive enough to require suturing for wound closure (<1.0 cm).	B/C-WD: Wound disruption extensive enough to require suturing or other clinical intervention but not surgery, (≥ 1.0 cm).	B/C-WD: Surgical re-exploration or repair is required, or referral/transfer to another facility or hospitalization is required.
Device	C-WD: Wound disruption but not extensive enough to require suturing for wound closure.	C-WD: Muco-cutaneous gap ≥ 1.0 cm in width, but no exposure of deeper tissue	C-WD: Wound disruption exposing tissue deeper than subcutaneous tissue or requiring surgical intervention such as suturing or debridement.

ADVERSE EVENT	MILD	MODERATE	SEVERE
OA: Other AEs, Excess swelling of penis/scrotum including haematoma; difficulty urinating; other			
Surgery (B/C-OA) and Device (A2/C-OA)	*Excess swelling*–mild swelling without signs of on-going bleeding. *Other*–N/A.	*Excess swelling*–symptoms/signs that require clinical intervention, but not surgical exploration. *Other*–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.	*Excess swelling*–surgical exploration required to control bleeding or remove haematoma 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. *Other*–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.
Difficulty urinating Surgery	NA	B/C-OA: 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).	B/C-OA: Complete obstruction and/or requires placement of a catheter, referral for treatment, or surgery to correct.
Difficulty urinating Device	NA	A2/C-OA: 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).	A1/C-OA: Complete obstruction and/or requires placement of a catheter, referral for treatment or surgery to correct.

APPENDIX 5: ANAESTHETIC DOSING

Starting and Maximum Doses Of 1.0% Lignocaine with and without Bupivacaine, By Volume

If bupivacaine to be used with lignocaine 1.0%, use concentration of 0.25% with 1:1 combination

Safe local anaesthetic dosing—starting* and *maximum*** volumes **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*.		

Safe local anaesthetic dosing—starting* and *maximum*** volumes

Mixture of 1% Lidocaine and 0.25% Bupivicaine

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/bupivicaine 0.3 mg/kg

***Maximum safe dose lidocaine 2.0 mg/kg/bupivicaine 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

Starting and Maximum Doses of 2.0% Lignocaine with and without Bupivacaine, by Volume
If bupivacaine to be used with lignocaine 2.0%, use concentration of 0.5% with 1:1 combination

Safe local anaesthetic dosing—starting* and *maximum*** volumes **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 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*.		

Safe local anaesthetic dosing—starting* and *maximum*** volumes

Mixture of 2% Lidocaine and 0.5% Bupivicaine

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)***

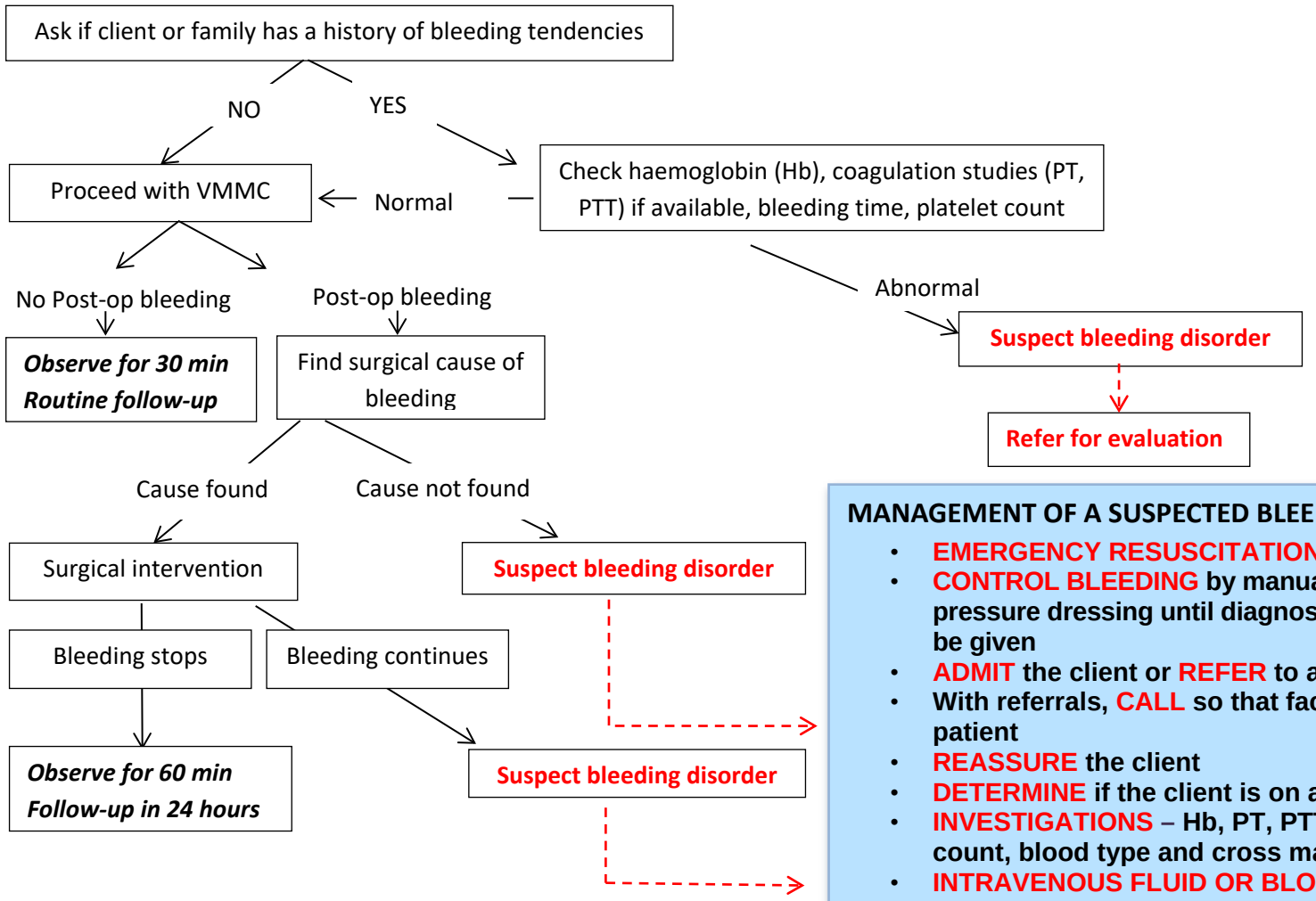
*Starting dose lidocaine 1 (lignocaine) .5 mg/kg/bupivicaine 0.3 mg/kg

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

***Use 5ml 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*.

APPENDIX 6: ALGORITHM FOR PREVENTION AND MANAGEMENT OF ACUTE BLEEDING DURING AND IMMEDIATELY AFTER MC, BY MC PROVIDERS

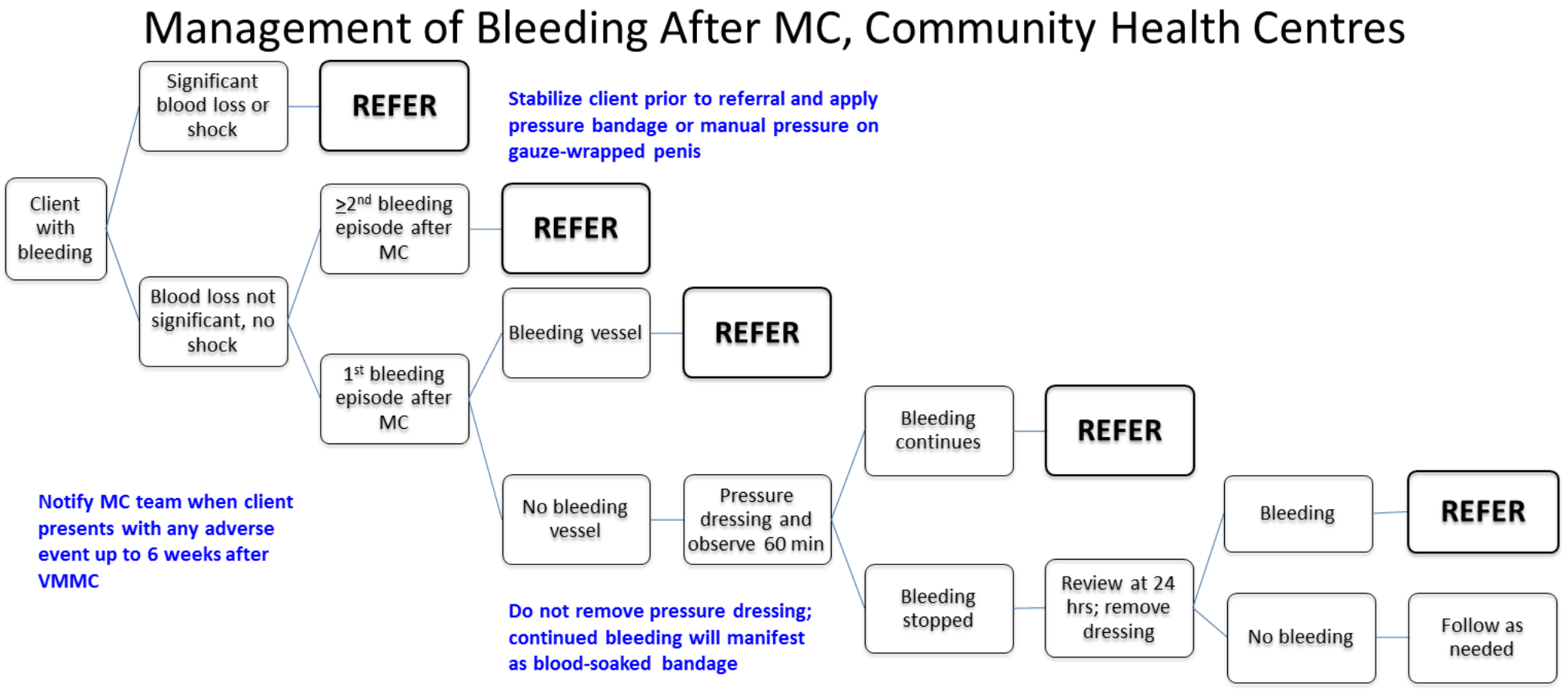


MANAGEMENT OF A SUSPECTED BLEEDING DISORDER:

- **EMERGENCY RESUSCITATION if in hypovolemic shock**
- **CONTROL BLEEDING by manual compression and/or pressure dressing until diagnosis and definitive treatment can be given**
- **ADMIT the client or REFER to a higher facility**
- **With referrals, CALL so that facility can get ready for the patient**
- **REASSURE the client**
- **DETERMINE if the client is on anticoagulant therapy**
- **INVESTIGATIONS – Hb, PT, PTT, bleeding time, platelet count, blood type and cross match**
- **INTRAVENOUS FLUID OR BLOOD TRANSFUSION if hypotensive since Hb may be normal after acute bleeding**
- **MANAGE according to the cause—e.g., Vitamin K, clotting factors, FFP, platelet transfusion etc.**

Adapted from JHPIEGO

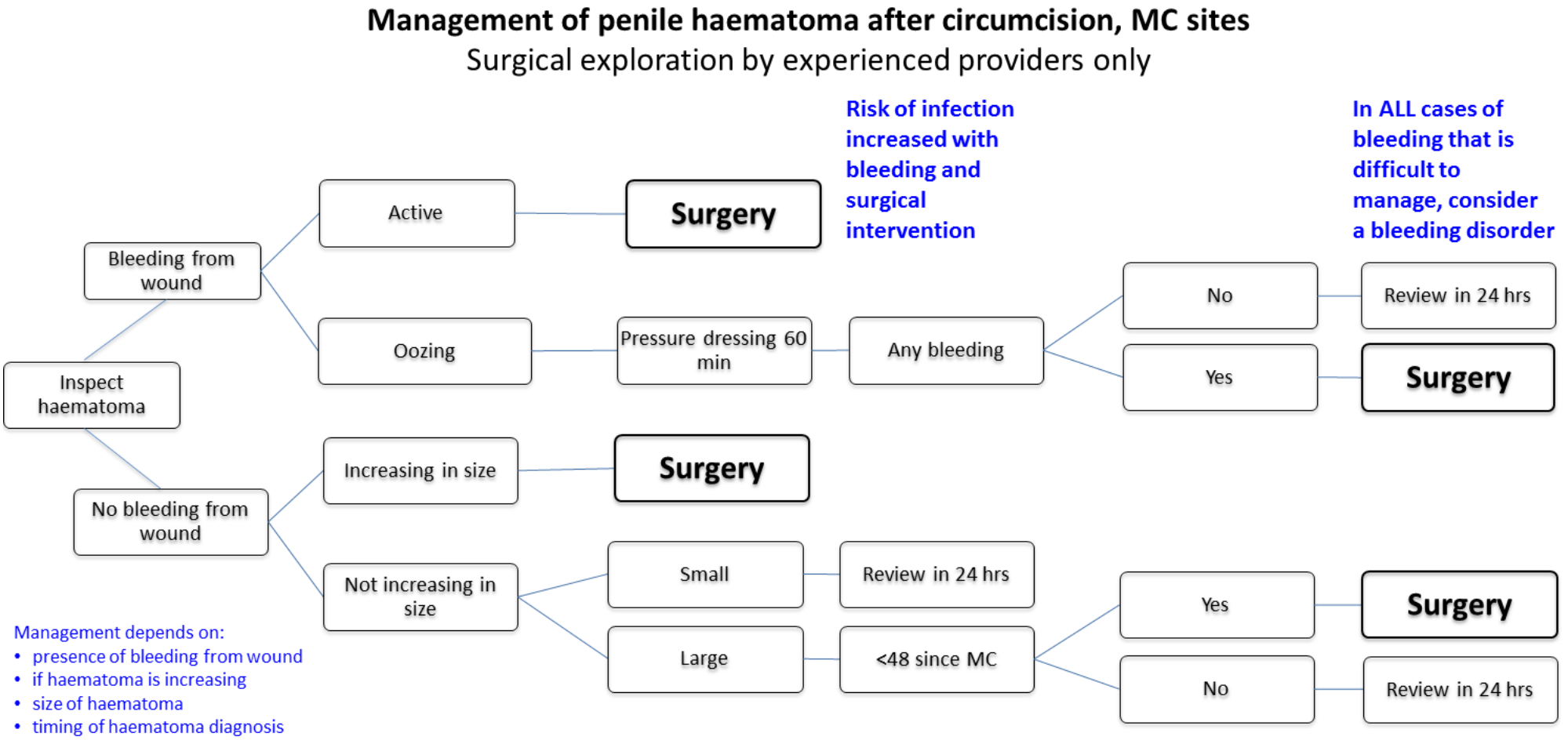
APPENDIX 7: ALGORITHM FOR MANAGEMENT OF BLEEDING AFTER MC, BY NON-MC PROVIDERS



In ALL instances of post-operative bleeding:

- **Each time a client presents with bleeding, check vital signs; if there is any indication of haemodynamic compromise, stabilize as possible and urgently refer.**
- **Obtain history from client/guardians about when bleeding started and estimated of blood loss.**
- **Ask client/guardians about trauma or other events that may have led to bleeding.**
- **Note if bleeding appears to be from a discreet area or vessel or from a large area of the surgical wound-diffuse bleeding more likely with a bleeding abnormality.**
- **Refer if there is a bleeding vessel identified as the source of bleeding. If staff with adequate surgical training and skill are available at the facility, may be managed onsite.**
- **Question client/guardian about a personal or family history of bleeding. (History may not have been obtained initially or client/guardian may have been reluctant to reveal history).**
- **Contact VMMC team to report AE during the time that the client is in clinic.**
- **When considering follow-up of a client with a bleeding, there should be consideration of travel distance and conditions required for a return visit. Difficulties, such as the need to walk considerable distance to the clinic may necessitate admission to a health care facility**.

APPENDIX 8: ALGORITHM FOR MANAGEMENT OF PENILE HAEMATOMA



APPENDIX 9: VMMC EMERGENCY MEDICAL SUPPLIES, EQUIPMENT AND MEDICINES

REQUIRED		HIGHLY RECOMMENDED
1. Stethoscope	9. Three sizes of oropharyngeal airways	17. Glucometer
2. Sphygmomanometer	10. Two sizes of syringes (2ml and 10ml)	18. Glucometer strips
3. Normal saline (sodium chloride solution for infusion; 0.9% NaCl)	11. Two sizes of needles (G21 and G23)	19. Paediatric blood pressure cuff
4. Tourniquet	12. Bags and masks (e.g., Ambu-bag) One child size One adult size	
5. IV infusion tubing	13. Exam gloves	
6. Three sizes of IV catheters (G18-green, G20-pink, G22-blue)	14. Alcohol swabs	
7. Adrenaline (unexpired)	15. Gauze	
8. Hydrocortisone (unexpired)	16. Adhesive tape (strapping)	