Adverse Event Action Guide

For Voluntary Medical Male Circumcision by Surgery

2014

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:

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PSI would like to acknowledge the contribution of:

Professor Stephen Ogendo, Vice President COSECSA and Chairman of the Department of Surgery Nairobi University; Professor Milliard Derbew, Assistant Secretary General, COSECSA and Chair of Paediatric Surgery Addis Ababa University; Professor Mohammed Labib, Chairman of Education and Scientific Committee COSECSA and Urologist, Namibia Medical School; Khumbulani Moyo, Abiodun Lamina, Gladys Magogo, Lindokuhle Mbhele, Duduzile Khumalo, Hayden Hawry, Jessica Greene, Thabo Mashigo, Sara Nieuwoudt, Petra Stankard, Jonathan Grund, and Stephanie Davis 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:

Kim Eva Dickson (United Nations Children's Fund), Julia Samuelson (WHO), Timothy Farley (WHO/ Sigma3 Services), Walter Obiero (Nyanza Reproductive Health Services, University of Illinois, Chicago), Elijah Odoyo-June (UNIM, or Universities of Nairobi, Illinois, and Manitoba trial), David Sokal (FHI 360), Timothy Hargreave (Consultant), Rebeca Plank (Harvard University), Stephen Watya (Mulago Hospital), Godfrey Kigozi (Rakai Health Sciences Program), Delivette Castor (U.S. Agency for International Development), Naomi Bock (CDC), and Kanyanta Sunkuntu (WHO Zambia).

April 14, 2014

TABLE OF CONTENTS

SECTION 1 – INTRODUCTION TO THE ADVERSE EVENT ACTION GUIDE

PURPOSE:

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

- Provide guidance on safe and appropriate management of AEs associated with voluntary medical male circumcision (VMMC),
- Facilitate standardized reporting, and
- Support monitoring of the quality of programmes and safety of VMMC services.

AUDIENCE:

The Guide has been prepared for VMMC programmes supported by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). These programmes are implementing VMMC under local anaesthesia in adolescent and adult males as part of a comprehensive HIV prevention strategy. The Guide is meant to be used by providers of VMMC services, including those who conduct post-operative reviews of clients but do not provide initial VMMC surgery.

GENERAL INFORMATION/KEY PRINCIPLES ABOUT THE GUIDE AND AES

AE general definition: ***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 at that time.***[1]

CLIENT SAFETY

VMMC is a surgical intervention being conducted on healthy males for personal and public health reasons. For this reason, a great level of client protection is needed. The Guide is written to ensure that client well-being is foremost at all times. In accordance with this philosophy:

- Surgical methods and techniques used should be in accordance with WHO "Manual for Male Circumcision under Local Anaesthesia."[2]
- Each facility should have a standard operating procedure (SOP) for a referral system including location, contact details, and follow-up procedures for care by a medical doctor who is competent with VMMC provision and will provide advice and treatment and/or a second opinion when needed.
- Serious Adverse Events (SAEs) should be reported to the senior physician and the VMMC national programme manager within 24 hours of discovery. Each country will have national guidelines on how to report SAEs.

[1] Specific definitions for each type of AE are provided in sections 2 and 3 and are based on PEPFAR definitions for VMMC AE.
[2] Found at http://www.who.int/hiv/pub/malecircumcision/who_mc_local_anaesthesia.pdf

AE CLASSIFICATION

AE classification has three components: severity, timing, and type. Severity and timing are defined here, and types are explained in detail in the management section.

AE SEVERITY:
AEs have been classified into three categories of severity—mild, moderate, and severe—to provide a clear spectrum of AEs. Only the moderate and severe AEs need to be reported and monitored according to PEPFAR guidance. This version of the Guide does not include AEs related to VMMC devices, which may have different characteristics and classifications. The Guide will be updated when that information is available.

- **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 PEPFAR 2013 monitoring and reporting guidelines require be reported.

AE TIMING:
In this guide, AEs are also 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)

By the nature of their natural history, not all AEs can occur at all time-points. For example, scarring can only be classified at point 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 tissue to develop.

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, though the presence of one AE may affect treatment for another (e.g., wound disruption should not be closed while untreated infection is present).

SERIOUS ADVERSE EVENT:[3]
A Serious Adverse Event (SAE) is a standard definition used across many types of interventions. In the context of AEs for VMMC, all AEs that meet criteria for severe should also be classified as SAEs. In addition, SAEs also include any event that:

- **Results in death**
- **Is life threatening**
- **May result in permanent disability or incapacitation (including deformity)**
- **Requires intervention to prevent permanent disability or incapacitation (including deformity)**
- **Requires hospitalisation or referral to a specialist for higher level care or intervention**

AE OUTCOMES/CONSEQUENCES:
AEs can have a number of outcomes, from resolution with no morbidity or permanent damage to outcomes that may include lengthy recovery periods and may result in permanent damage such as scarring. One purpose of the Guide is to limit the severity of AEs and improve the outcomes.

HOW TO USE THIS GUIDE

The Guide follows the structure indicated here. This course of action can apply to any AE.

1. **Identification:** The health care worker providing care should first identify and classify the AE. **The AE may be revealed by the client or the provider during surgery, post-operative observation period, or at a subsequent visit.** While cell phone communication about healing during the post-operative period is acceptable, all AE identification and treatment must be conducted through direct observation by a clinician. A list of the various types of VMMC-related AEs, as well as definitions of the respective severity levels, can be found in Section 3.
2. **Treatment:** Once the AE is identified and classified, the provider is encouraged to follow the treatment guidelines in this Guide. However, where national protocols exist, they should be prioritized. Successful treatment depends on the provider understanding the type and severity of the AE, taking prompt action, and requesting the necessary assistance from other providers or health facilities. Please note that the medications mentioned in this Guide, specifically antibiotics, are given as examples only. Local availability, drug resistance patterns, and national treatment protocols may vary. Thus, national programmes should adapt the guidance accordingly.

3. **Referral, if necessary:** Referral to another health facility or provider (e.g., specialist doctor) may be necessary**.** 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

[3] Source: http://www.fda.gov/safety/medwatch/howtoreport/ucm053087.htm

that it is up to date. These providers and sites should be aware of the possibility of VMMC clients being referred for assistance. 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.

4. **Reporting:** Proper reporting is important so that: 1) providers can follow up with the client as necessary, and 2) managers and providers can monitor the quality and safety of a programme and take actions to improve client care. Providers need to understand and follow the AE reporting guidelines. Site and programme managers must understand how and when to report AEs and when to inform external stakeholders. Reporting should follow nationally prescribed reporting pathways and protocols. PEPFAR-funded programmes should report AEs in accordance with PEPFAR reporting requirements.

5. **Follow-up:** Routine follow-up ensures that clients receive sufficient care after surgery. 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.

SECTION 2 – TREATMENT GUIDELINES FOR ADVERSE EVENTS IN MALE CIRCUMCISION

EXCESSIVE BLEEDING

VMMC-related bleeding AEs most typically occur in the first 72 hours after surgery. Bleeding-related AEs occurring after 72 hours are often associated with trauma to the genital area or early commencement of masturbation or sexual intercourse. The primary cause of these AEs is a previously unidentified or newly disrupted bleeding vessel.

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

- On-going intra-operative or immediate postoperative bleeding (classified as A)
- Post-operative bleeding (classified as B or C, though significant bleeding is very unlikely after 72 hours)

Bleeding can be difficult to control in clients with bleeding abnormalities. The most common of these abnormalities are von Willebrand Disease and haemophilia, and it is important for providers to question the client or, in the case of a minor, the parent or guardian, if there is a history of bleeding problems. If there is a history of a bleeding abnormality, VMMC should not be undertaken. If there is uncertainty about whether a bleeding abnormality is present, there should be consultation with a specialist before VMMC. It is important to remember that in some people with milder forms of these bleeding abnormalities, the problem becomes apparent only after there is a medical intervention such as an operation or a dental procedure. VMMC may be the first medical procedure that some clients undergo, especially younger clients, and may be the instance where a previously undiagnosed bleeding abnormality becomes apparent.

It is very important to consider a bleeding abnormality in a client with prolonged bleeding, even if there is no history of this. In cases where a bleeding abnormality is suspected, the client should be referred for specialist medical and surgical care. In the case of a client who returns for recurrent bleeding more than once after surgery, a bleeding abnormality should be suspected and the client should be referred for specialist care.

INTRA-OPERATIVE (OR PRIOR TO DISCHARGE FROM CLINIC) BLEEDING

Defined as: Oozing/swelling/obvious bleeding after initial surgery

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

Look for:

- Unidentified bleeding vessel, commonly occurring in the region of the frenulum. This bleeding can be difficult to stop and best controlled with ligatures and **not** diathermy cautery, since the area of the frenulum and the underlying urethra is vulnerable to cautery-related burns.
    - 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 and potential to cause future urethral stricture or fistula.
- Overly deep dissection with the scalpel blade or dissecting scissors into the highly vascular corpus cavernosa or other deep vascular penile tissue.
- Excessive bleeding during surgery or immediately thereafter may increase the risk for subsequent wound infection; close follow-up (e.g., visits at day 2 and day 4 or 5) to ensure that infection does not develop may be needed.

In <u>all</u> cases:

- **Stay calm and remember that it is almost always possible to control bleeding with manual pressure while determining next steps or calling for assistance.**
- **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.

ADVERSE EVENT	MILD	MODERATE	SEVERE
Excessive Bleeding ***Intra-operative or prior to discharge from clinic***	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.
TREAT	• Apply pressure manually with gauze swab and maintain for 5 minutes. • Gently remove swab. If bleeding has stopped, reapply the wound dressing. • If bleeding continues, this is a moderate AE.	• Apply pressure manually with gauze swab and maintain for 5 minutes. • 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. • Administer local anaesthesia if necessary. • If the 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 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.**	• **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.

POST-OPERATIVE EXCESSIVE BLEEDING

Defined as: Oozing/obvious bleeding after discharge from VMMC clinic

- Minor post-operative bleeding may be related to removal of dressings and 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.
- Moderate to severe post-operative bleeding usually presents from 6 hours after surgery to the first post-operative day, but can occur even later and may be due to a cauterized or transfixed 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, likely having soiled the previous dressings and underwear substantially. If this bleeding is contained or partially contained by the suture margin, there may be accompanying swelling or underlying haematoma. This presents as either swelling without bleeding, swelling with bleeding, or bleeding without swelling.
- Fresh, noticeable active bleeding not controlled by pressure dressing requires re-operation.
    - **Caution: Any bleeding or haematoma that recurs more than once could indicate a bleeding abnormality and should be referred for further evaluation.**
- Also see “Other Adverse Events” if there is swelling or haematoma.

ADVERSE EVENT	MILD	MODERATE	SEVERE
Excessive Bleeding ***Post-operative***	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.	B/C-BL: Bleeding that is not controlled by new dressings or 5–10 minutes of manual pressure, 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.
TREAT	• Control with new dressings or 5–10 minutes of manual pressure. • Apply a light pressure dressing and observe the client for 30 minutes to ensure bleeding does not resume. • Review in 24 hours.	• Apply pressure manually with gauze swab and maintain for 5 minutes. • 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 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.	• 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 penis that can result in penile engorgement and further bleeding.

INFECTION

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

Infection-related AEs typically present in the first two weeks following surgery (timing classification B or C); however, problems related to effects of severe wound infections can present months or even years later. The degree of wound infection encompasses a broad spectrum of severity ranging from mild/moderate manifestations of wound infections, including 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. Infections are classified as mild, moderate, or severe and may present starting at the second postoperative day. 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 should not be used.

NOTE: There are separate classifications for treatment of wound disruption and scarring/disfigurement later in this section.

Look for:

- Suture margin discharge that is serous or frank pus
- Suture margin infection identified by small areas of yellow slough often around a suture itself or the area of the frenulum

Enquire about:

- When the signs of infection were first noted
- Wound hygiene and cleaning practices
- Pain
- Self-administered treatment

A localized swollen, fluctuant area (often this swelling is extremely tender to palpation), warmth of affected area, offensive odour, and/or thick yellow discharge may indicate the presence of an abscess and may require surgical drainage and treatment with antibiotics***.***

ADVERSE EVENT	MILD	MODERATE	SEVERE
Infection	B/C-IN: Erythema or traces of serous discharge or infective process noted at wound margin. No medication required 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 antibiotic therapy.
TREAT	• 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.	• Explain and emphasize importance of keeping the wound clean for favourable outcomes in the recovery/healing period. • If area of erythema confined to near wound edges and discharge is minimal, local wound care may be sufficient to treat infection. • 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 to 3 day intervals until healing is complete. • **Advise any client with infection to contact centre if pain or other symptoms such as fever worsens.**	• 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. • Support penis against gravity by supporting it 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 may be useful to release 1–2 sutures in the hope that pus will drain. But 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.

WOUND DISRUPTION

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

- Wound disruption may follow either the unravelling of a suture (possibly poorly placed or tied), premature dissolution of an absorbable suture, or infection of the wound that involved swelling and separation of the edges. Too tight knotting of the suture can cause ischemia 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).
- Once clean and infection-free, even wounds with large defects can granulate well without need for secondary suturing for closure. As healing by granulation can lead to scar formation and deformity, secondary closure after wound is clean and infection-free is advised.

Wound disruption timing is classified as B or C only.

ADVERSE EVENT	MILD	MODERATE	SEVERE
Wound Disruption	B/C-WD: Wound disruption but not extensive enough to require suturing for wound closure.	B/C-WD: Wound disruption extensive enough to require suturing or other clinical intervention (but not surgery).	B/C-WD: Surgical re-exploration or repair is required, or referral/transfer to another facility or hospitalization is required.
TREAT	• Generally, dehiscence measuring less than 1 cm in length 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.	• Generally, dehiscence measuring less than 1 cm in length does not require additional sutures. • If wound dehiscence without signs of infection, apply additional sutures. • 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. Consider applying additional sutures once infection has cleared.	• **REFER** for further treatment in a surgical unit.

PAIN

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

Pain is a difficult and subjective sensation to classify. People have different thresholds of pain and trying to classify and describe pain as mild, moderate, or severe is challenging. Pain is also a normal event associated with any surgery and VMMC is no exception.

INTRA-OPERATIVE PAIN

Because it is a surgical procedure, VMMC results in pain and requires pain 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, there may be inappropriate injection technique leading to intravascular administration of the drug rather than into the local area requiring anaesthesia, or that the anaesthetic agent may be of poor quality and not contain the amount of anaesthetic stated on the label; consider using a different bottle or lot of drug.

ADVERSE EVENT	MILD	MODERATE	SEVERE
Pain ***Intra-operative or prior to discharge from clinic***	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.
TREAT	• Mild pain and/or discomfort is expected when one gets an injection, and therefore not reported.	• Give additional local anaesthetic while remaining within maximum safe dose.	• Postpone procedure to another day and investigate the cause of the pain.

POST-OPERATIVE PAIN

The average VMMC client will report pain 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 erections that often occur in the early morning 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.

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

- Does not resolve even with analgesia
- Report of significant sleep disruption 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 resolved significantly 7–10 days after surgery
- Pain gets progressively worse and not better after surgery
- Pain is associated with another type of AE (e.g., infection)

Providers need to use their experience, training, and these guidelines to decide if there is abnormal pain beyond the pain associated with VMMC.

ADVERSE EVENT	MILD	MODERATE	SEVERE
Pain ***Post-operative***	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**.**
TREAT	• Reassure client and administer oral analgesic agents such as Paracetamol (Acetominophen) or Ibuprophen.	• 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.	• 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.

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:

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

All of these should be reported under the appropriate AE of scarring/disfigurement/poor cosmetic result; excess skin removal; injury to penis. In the cases of scarring/disfigurement and insufficient skin removal, full assessment cannot be made until more than 7 days after surgery and therefore all cases are classified as C. 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.

SCARRING/DISFIGUREMENT

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

This can only be classified as C, as an 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 the sutures have been absorbed, 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 and torsion of the penis, 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 where a circumcision is carried out and areas that do should be avoided during circumcision. If a keloid is suspected, repair or removal should be performed 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 significant ridging and management should be as described below.

ADVERSE EVENT	MILD	MODERATE	SEVERE
Scarring/ Disfigurement	C-SD: Complaints by client in the absence of discernible abnormal scarring/disfigurement.	C-SD: Discernible but re-operation not required.	C-SD: Discernible and requires re-operation or referral/transfer to another facility.
TREAT	• Reassure client that with healing of the wound, the appearance of the penis will improve.	• Reassure client that with healing of the wound, the appearance of the penis will improve.	• **REFER** to a specialist/urologist who may consult a plastic surgeon in cases of severe scarring or disfigurement.

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 rare and 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). There is no corresponding line on the dorsal (uppermost) side of the penis. Some torsion is caused by excess skin removal that is compensated for intraoperatively by moving the remaining skin about.

Some torsion may only be present 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 is noted while applying the dressings at the end of the procedure, remove all the sutures and start again. 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 B or C.

ADVERSE EVENT	MILD	MODERATE	SEVERE
Torsion of penis	B/C-SD: Torsion present but does not cause pain or discomfort.	B/C-SD: Torsion present that causes mild pain or discomfort with erection but does not require surgery to correct.	B/C-SD: Torsion present. Erections are painful and client cannot tolerate the appearance, discomfort, or pain. Surgery needed for correction.
TREAT	• 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.	• 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.	• **REFER** to a specialist for potential re-operation.

INSUFFICIENT SKIN REMOVAL

Defined as: A state where the skin at the coronal sulcus partially covers the glans. To correctly assess the accuracy of the amount of foreskin excised, providers need to observe the penis in a flaccid state once operative swelling has completely subsided and without pulling on the remaining foreskin. Therefore this AE can only be classified as C.

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*.

Signs of insufficient skin removal include:

- The glans of the penis is partially covered by residual foreskin and not completely exposed.
- The foreskin may cover the coronal ridge and perhaps even a greater portion of the glans.

Clients with insufficient skin excision often present dissatisfied and complain of a poor cosmetic result. Ideally, insufficient skin removal should be noted and addressed at the time of initial surgery so that re-operation is not required. If it is noted at the time of the procedure that insufficient skin has been removed (e.g., with the forceps-guided method, one can see a wide margin of inner foreskin remaining and the shaft skin can easily be stretched to cover the glans or part of it) correction can be made at that time. 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. If insufficient skin removal is not noted until after surgery, re-operation may be needed and may require a sleeve technique and should be carried out only by a provider experienced in that technique.

ADVERSE EVENT	MILD	MODERATE	SEVERE
Insufficient skin removal	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 partially covers glans when flaccid and surgical correction is necessary.
TREAT	• Reassure the client; no further action needed.	• 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 VMMC provider for re-circumcision by sleeve resection in a hospital.	• 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 VMMC provider for re-circumcision by sleeve resection in a hospital setting.

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. Early referral for skin grafting can decrease scar formation.

Extreme care should be taken to preventing 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.
- Tension on sutures when approximating the shaft skin and mucosal edge.
- A gaping wound with edges impossible to approximate.

INTRA-OPERATIVE EXCESS SKIN REMOVAL

ADVERSE EVENT	MILD	MODERATE	SEVERE
Excess Skin Removal ***Intra-operative***	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.
TREAT	• 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. • Regular follow-up to ensure good wound healing and review the integrity of the suture margin. • It may be necessary to see some clients 6–12 months post circumcision after complete wound healing. In most cases, tightness with erections will resolve by the time the wound has completely healed 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 skin graft to help close the wound.

POST-OPERATIVE EXCESS SKIN REMOVAL

ADVERSE EVENT	MILD	MODERATE	SEVERE
Excess Skin Removal ***Post-operative***	B/C-SD: Slight tightening of the skin observed; no surgical correction needed.	B/C-SD: Tightness of the skin discernible and additional sutures or skin mobilisation needed for wound closure, but no other intervention needed.	B/C-SD: Re-operation or referral/transfer to another facility required.
TREAT	• Reassure client that most skin tightening and mild pain on erection resolves as skin on the wound stretches.	• Additional sutures by an experienced operator on site; if experienced operator not available refer to another health care facility. • Regular follow-up to ensure good wound healing and review the integrity of the suture margin. • It may be necessary to see some clients 6–12 months post circumcision after complete wound healing. In most cases tightness with erections will resolve by the time the wound has completely healed but a small number of cases will need referral for plastic surgery (severe AE).	• 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. • **REFER** to a higher-level health care facility.

INJURY TO PENIS

Defined as: Injuries to the penis or complications due to the actions of the surgeon

This category includes:

1. **Damage to the glans or shaft of the penis or any part of the genitalia caused by an instrument, normally the scalpel (i.e., lacerated or severed tissue).** Due to the vascular nature of the penis, damage to the glans or shaft can lead to significant bleeding.

2. **Damage to the glans or shaft of the penis or any part of the genitalia caused by a cautery device generating heat (i.e., electrocautery/diathermy burns).** This is a rare complication caused by incorrect use of diathermy (e.g., by attempting to cauterize a vessel close to or under the mucosal or skin margins, or by applying diathermy current on too much tissue or for too long). Heat transfer may occur quickly, resulting in a burn to the mucosa or the urethra. Very rarely, prolonged use of the diathermy can result in coagulation of the entire penile shaft. Bleeding vessels in the vicinity of mucosal or skin margins or the frenulum should be ligated or sutured **using sutures and not diathermy**. Small mucosal burns result in the tissue becoming devitalized, which may turn to slough and become infected.

INTRA-OPERATIVE INJURY TO PENIS

ADVERSE EVENT	MILD	MODERATE	SEVERE
Injury to Penis ***Intra-operative***	A-SD: Limited superficial laceration or burn injury not requiring additional dressings.	A-SD: Abrasion of glans or shaft or small burn injury requiring prolonged intra-operative attention to treat or pressure dressing, but surgical repair beyond suturing not required.	A-SD: Requires additional surgical intervention to stop bleeding or to repair. Severing of the glans or shaft, damage to the urethra or significant burn injury also a severe AE.
TREAT	**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.	**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.	**Damage caused by scalpel:** • **REFER** for treatment monitoring and evaluation. If a portion of the tissue has been severed and bleeding is profuse or if the injury is in the vicinity of the urethra, apply a pressure dressing. Severed tissue should be sent with the client preferably within the dressings. **Damage caused by cautery:** • **REFER** for treatment monitoring and evaluation especially for clients sustaining larger burns in the vicinity of the urethra.

POST-OPERATIVE INJURY TO PENIS

ADVERSE EVENT	MILD	MODERATE	SEVERE
Injury to penis ***Post-operative***	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.	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, transfer or transfusion; or significant burn injury leading to significant tissue necrosis/loss.
TREAT	**Damage caused by cautery:** • Apply paraffin gauze to affected areas and repeat daily dressing until complete healing.	**Damage caused by cautery:** • Apply paraffin gauze to affected areas and repeat daily dressing until complete healing. • Start on prophylactic treatment with antibiotics, such as amoxicillin/clavulanic acid, or in accordance with national guidance or locally available drugs.	**Severe AE should have been noted at the time of surgery and should have been referred at that time. However, should there be signs of severe injury in the post-operative period, refer to a specialist.**

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

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

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 has resolved or may be ongoing. Swelling or haematoma should be classified as B or C. If it is associated with ongoing bleeding or infection, these AEs should also be reported.

With haematoma:

- Increased swelling or extension of the haematoma into adjacent tissues indicates ongoing bleeding.
- The presence of a haematoma may be indicated by a dusky appearance of the skin, indicating underlying blood.
- Haematomas without active bleeding should resolve spontaneously and can be treated conservatively.
- If 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 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.

Any haematoma that recurs more than once could indicate a bleeding abnormality and should be referred for further evaluation.

With swelling **not** associated with haematoma:

- Swelling is part of the healing process and should resolve over time.
- Increasing swelling can be an indication of a problem such as infection and may be indicated by accompanying drainage from wound, surrounding erythema or warmth.
- If infection is suspected, follow closely and consider starting oral antibiotics (see also above under “Infection”).

ADVERSE EVENT	MILD	MODERATE	SEVERE
Excess swelling of penis/scrotum including haematoma	B/C-OA: Mild swelling without signs of on-going bleeding.	B/C-OA: Symptoms/signs that require clinical intervention, but not surgical re-exploration.	B/C-OA: Surgical re-exploration required to control bleeding or remove haematoma, or symptoms or 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.
TREAT	• 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.	**IF ONGOING BLEEDING IS PRESENT, CLASSIFY AS SEVERE.** **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.	**IF BLEEDING IS PRESENT:** • 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 explore 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 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

ADVERSE EVENT	MILD	MODERATE	SEVERE
			against the abdominal wall to help the swelling resolve. A period of rest may help the swelling resolve.

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 that he:

- Cannot pass urine but has an urge to do so after more than 6–8 hours have passed since surgery, or
- Is passing small amounts of urine on a frequent basis, or
- Is only managing a trickle following heavy straining.

Causes of inability to void can range from pain and apprehension to inadvertent ligation of the urethra. Common 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. With moderate voiding, there is partial obstruction with either the client 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. Rarely, a man with a pre-existing urethral stricture will have this revealed as voiding difficulties after the procedure.

A deep suture applied across the urethra may cause difficulty with urination and is more commonly seen in infants and small boys; however, adult cases have been reported. If enough time has passed, the suture may be covered by swollen skin edges. Removal of the bandage does not relieve symptoms and fullness in the bladder or urethra will be palpable on asking the client to pass urine (the urethra proximal to the blockage may fill with urine and bulge as urination is attempted). Inability to pass a small catheter will confirm the clinical impression. Catheterization may be necessary**. Use size 10–12 Fr (French Size) for boys and men aged 10 years onwards.**

ADVERSE EVENT	MILD	MODERATE	SEVERE
Problem with Voiding (Urinating)	B/C-OA: Partial obstruction that is transient in nature.	B/C-OA: Partial 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 a moderate AE).	• B/C-OA: Complete obstruction and/or requires placement of a catheter, referral for treatment, or surgery to correct.
TREAT	• Check the dressing pressure; if too tight replace with a bandage with correct pressure. A bandage that is too tight is where one cannot insert a finger between the bandage and the skin. (This definition does not apply in the case of a pressure dressing that is being used to achieve haemostasis). • Ensure the client drinks plenty of fluids (at least 3 litres per day).	• 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 be classified as severe. • If a catheter is required for less than 24 hours, providers may wish to classify this as moderate.	• **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, insert a supra pubic catheter.

SEXUAL COMPLICATIONS/UNDESIRABLE SENSORY CHANGES

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

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 also to 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 is derived from the history given by the client. 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 of the areas of sensory changes and use the diagram at each visit to determine changes over time.

The sexual effect of circumcision 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 newly “exposed” glans epithelium is not yet cornified. This effect is most likely temporary and will resolve with 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 resolves. This resolution interval will vary among individuals.

Some reports have suggested that circumcision may contribute to erectile dysfunction. 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 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 postoperative period.

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

ADVERSE EVENT	MILD	MODERATE	SEVERE
Sexual Complications/ Undesirable sensory changes	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.
TREAT	• Reassure client and explain that increased sensitivity is common for the first month or two after VMMC. • 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.	• 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.	• **REFER** all cases to a specialist.

ANAESTHESIA-RELATED EVENTS

Lidocaine (Lignocaine) is an amide local anaesthetic. Lidocaine 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 a number of programmes, a mixture of bupivacaine (Marcaine) and lidocaine is used for local anaesthesia because the mixture provides a longer duration of anaesthesia than lidocaine alone. The mechanism of action and toxicity of bupivacaine are the same as those of lidocaine.

SYSTEMIC TOXICITY FROM LOCAL ANAESTHESIA:

This is very rare and occurs with unintended intravascular administration or with administration of an excessive dose**. This is one of the most serious AEs that can be seen, is difficult to treat successfully, and it is essential to prevent through:**

- Know the toxic dose of the local anaesthetics being used and use the lowest effective dose. The doses of these agents are weight-based and differ for different sized individuals.
- 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 lidocaine and bupivacaine come in at least two concentrations.
- **ALWAYS aspirate before EVERY injection of an anaesthetic agent** 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.

LOCAL 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 lidocaine alone while others use lidocaine and bupivacaine because the combination results in rapid onset of action and longer duration of anaesthetic effect
- Standardization of the concentration of anaesthetic agents used; two commonly used concentrations of lidocaine (1.0% and 2.0%) and bupivacaine (0.25% and 0.5%) are available and there is 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
- Standardization of the mixing process of the combination of anaesthetic agents
- 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 advantage of lidocaine is that it works rapidly. An alternative is a mixture of lidocaine and bupivacaine—this is more expensive than lidocaine alone but has the advantage of providing longer lasting anaesthesia (up to 4–5 hours after the operation).

The maximum recommended dose is 3.0 mg/kg for lidocaine and 1.5 mg/kg for bupivacaine when either agent is used alone. Adequate anaesthesia can be achieved with lower doses and when combined, such that the maximum recommended dose is 2.0 mg/kg of lidocaine and 0.5 mg/kg of bupivacaine (when used together).

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 lidocaine 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.

Tables 2 and 3 give volumes of **maximum doses** of lidocaine, used with and without bupivacaine. 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. **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 sufficient for a 40 kg client, even though a higher maximum dose/volume may be allowed. This is because area of tissue that needs to be anesthetized for circumcision is relatively limited. With use of 2.0% lidocaine 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.

Inadequate pain control should not occur in the context of surgical VMMC. 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: Milligrams per Millilitre of Local Anaesthetic

Agent	mg/ml
lidocaine 1.0%	10 mg/ml
lidocaine 2.0%	20 mg/ml
bupivacaine 0.25%	2.5 mg/ml
bupivacaine 0.5%	5.0 mg/ml

Table 2: Maximum Doses of 2.0% Lidocaine with and without Bupivacaine, by Volume

Weight (kg)	Lidocaine 2.0% with and without Bupivacaine[1]		
	Lidocaine 2%[2]	Lidocaine 2.0% / Bupivacaine 0.5%[3,4]	Lidocaine 2.0% / Bupivacaine 0.25%[3,4,5] *This combination likely rare; this is NOT a 1 to 1 mix; use extreme caution*
30	4.5 ml	3.0 ml / 3.0 ml	3.0 ml / 6.0 ml
35	5.0 ml	3.5 ml / 3.5 ml	3.5 ml / 7.0 ml
40	6.0 ml	4.0 ml / 4.0 ml	4.0 ml / 8.0 ml
45	6.5 ml	4.5 ml / 4.5 ml	4.5 ml / 9.0 ml
50	7.5 ml	5.0 ml / 5.0 ml	5.0 ml / 10.0 ml
55	8.0 ml	5.5 ml / 5.5 ml	5.5 ml / 11.0 ml
60	9.0 ml	6.0 ml / 6.0 ml	6.0 ml / 12.0 ml
65	10.0 ml	6.5 ml / 6.5 ml	6.5 ml / 13.0ml
70	10.5 ml	7.0 ml / 7.0 ml	7.0 ml / 14.0 ml
75	11.0 ml	7.5 ml / 7.5 ml	7.5 ml / 15.0 ml
80	12.0 ml	8.0 ml / 8.0 ml	8.0 ml / 16.0 ml
85	12.5 ml	8.5 ml / 8.5 ml	8.5 ml / 17.0 ml
90	13.5 ml	9.0 ml / 9.0 ml	9.0 ml / 18.0 ml

[1] Lidocaine 2.0% is preferred. If bupivacaine to be used in combination with lidocaine 2.0%, preferred concentration is 0.5%.
[2] When used as a single anaesthetic agent, the maximum dose of lidocaine used should be 3.0 mg/kg.
[3] When used in combination, the maximum dose of lidocaine used should be 2.0 mg/kg and the maximum dose of bupivacaine used should be 0.5 mg/kg.
[4] Bupivacaine should not be given to any person who weighs less than 30 kg.
[5] Before dosing with a combination of 2.0% lidocaine and 0.25% bupivacaine, be absolutely certain the bupivacaine concentration is 0.25%; accidental use of 0.5% bupivacaine in the larger volumes will result in over-dosage.

Table 3: Maximum Doses of 1.0% Lidocaine with and without Bupivacaine, by Volume

Weight (kg)	Lidocaine 1.0% with and without bupivacaine[1,6]		
	Lidocaine 1.0%[2]	Lidocaine 1.0% / Bupivacaine 0.5%[3,4] This combination likely rare; this is NOT a 1 to 1 mix use extreme caution	Lidocaine 1.0% / Bupivacaine 0.25%[3,4,5]
30	9.0 ml	6.0 ml / 3.0 ml	6.0 ml / 6.0 ml
35	10.5 ml	7.0 ml / 3.5 ml	7.0 ml / 7.0 ml
40	12.0 ml	8.0 ml / 4.0 ml	8.0 ml / 8.0 ml
45	13.5 ml	9.0 ml / 4.5 ml	9.0 ml / 9.0 ml
50	15.0 ml	10.0 ml / 5.0 ml	10.0 ml / 10.0 ml
55	16.5 ml	11.0 ml / 5.5 ml	11.0 ml / 11.0 ml
60	18.0 ml	12.0 ml / 6.0 ml	12.0 ml / 12.0 ml
65	19.5 ml	13.0 ml / 6.5 ml	13.0 ml / 13.0 ml
70	21.0 ml	14.0 ml / 7.0 ml	14.0 ml / 14.0 ml
75	22.5 ml	15.0 ml / 7.5 ml	15.0 ml / 15.0 ml
80	24.0 ml	16.0 ml / 8.0 ml	16.0 ml / 16.0 ml
85	25.5 ml	17.0 ml / 8.5 ml	17.0 ml / 17.0 ml
90	27.0 ml	18.0 ml / 9.0 ml	18.0 ml / 18.0 ml

[1] Lidocaine 2.0% is preferred.
[2] When used as a single anaesthetic agent, the maximum dose of lidocaine used should be 3.0 mg/kg.
[3] When used in combination, the maximum dose of lidocaine used should be 2.0 mg/kg and the maximum dose of bupivacaine used should be 0.5 mg/kg.
[4] Bupivacaine should not be given to any person who weighs less than 30 kg.
[5] Before dosing with a combination of 1.0% lidocaine and 0.25% bupivacaine, be absolutely certain the bupivacaine concentration is 0.25%; accidental use of 0.5% bupivacaine in the larger volumes will result in over-dosage.
[6] Before dosing with 1.0% lidocaine (alone or in combination), be absolutely certain the lidocaine concentration is 1.0%; accidental use of 2.0% lidocaine in the larger volumes will result in over-dosage.

ANAPHYLAXIS TO LOCAL ANAESTHETIC AGENTS:

This is extremely rare and should not be confused with overdose of local anaesthetic.

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 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.

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, are self-limited and resolve. Treatment consisting of reassurance, laying the client down, elevation of legs, close observation, and, on occasion, oxygen may be required until clients recover. Vasovagal reactions should not be mistaken for toxicity to anaesthetic agents.

HYPOGLYCEMIC 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.

ADVERSE EVENT	MILD	MODERATE	SEVERE
Anaesthesia-related event	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.
TREAT	• Stop the injection immediately and prepare to treat the reaction.	• Stop the injection immediately and prepare to treat the reaction.	• 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 cardiopulmonary functions stable.**

SECTION 3 – APPENDICES
ADVERSE EVENT RECORDING AND REPORTING

All AEs should be reported, even if they do not have a single cause. For example, wound disruption that is caused by an infection should be reported as two AEs: infection and wound disruption.

MOST COMMON TYPES OF AEs RELATED TO VMMC:

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

All AEs must be recorded and include time, type, and severity, as defined below.

Time	Type	Severity
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)	**AN** = Problem with **An**aesthesia **BL** = Excessive **Bl**eeding **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** = **S**e**x**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)	Mild Moderate Severe

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

OCCUPATIONAL EXPOSURE (HEALTH CARE PROVIDERS)—Occupational exposure, for example from a needle stick injury, is an important risk to the provider. 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://whqlibdoc.who.int/publications/2007/9789241596374_eng.pdf).

AE CLASSIFICATIONS AND DEFINITIONS: DURING SURGERY OR PRIOR TO DISCHARGE FROM VMMC CLINIC

ADVERSE EVENT	MILD	MODERATE	SEVERE
AN: Anaesthetic-related problem	A-AN: Mild localised allergic reaction at injection site without swelling and systemic reaction.	A-AN: 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.	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.
BL: Bleeding	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.
OT: Occupational exposure (health providers)	N/A	A-OT: All occupational exposures are classified as moderate.	N/A
PA: Pain	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 or pain that results in early termination of surgery.	A-PA: Pain not responsive to additional local anaesthesia. Sedation or general anaesthesia would be required, therefore procedure is best postponed to another day.

ADVERSE EVENT	MILD	MODERATE	SEVERE
SD: Scarring/disfigurement/poor cosmetic result; excess skin removal; injury to penis	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. A-SD: • *Injury to penis*–abrasion 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*–requires additional surgical intervention to stop bleeding or to repair. Severing of the glans or shaft, damage to the urethra, or significant burn injury also a severe AE.

AE CLASSIFICATIONS AND DEFINITIONS: POST-OPERATIVE PERIOD AFTER DISCHARGE FROM VMMC CLINIC

ADVERSE EVENT	MILD	MODERATE	SEVERE
BL: Bleeding	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.	B/C-BL: Bleeding that 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/intravenous fluid necessary.
IN: Infection	B/C-IN: Erythema, or traces of serous discharge, or infective process noted at wound margin. No medication required 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 antibiotic therapy.
PA: Pain	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.
SD: Scarring/disfigurement/ poor cosmetic result; excess skin removal; injury to penis	B/C-SD: • *Scarring/disfigurement*–complaints by client in the absence of discernible abnormal scarring/disfigurement. Can only be classified as C. • *Torsion of penis*–torsion present but does not cause pain or discomfort. • *Insufficient skin removal*–prepuce extends over the coronal margin but less than one third of the glans is covered in flaccid state. Can only be classified as C. • *Excess skin removal*–slight tightening of	B/C-SD: • *Scarring/disfigurement*–discernible but re-operation not required. Can only be classified as C. • *Torsion of penis*–torsion present that causes mild pain or discomfort with erection but does not require surgery to correct. • *Insufficient skin removal*–prepuce partially covers glans when flaccid but surgical correction is not necessary. Can only be classified as C. • *Excess skin removal*–tightness of the skin	B/C-SD: • *Scarring/disfigurement*–discernible and requires re-operation or referral/transfer to another facility. Can only be classified as C. • *Torsion of penis*–torsion present. Erections are painful and client cannot tolerate the appearance, discomfort, or pain. Surgery needed for correction. • *Insufficient skin removal*–prepuce partially covers glans when flaccid and surgical correction is necessary. Can only be classified as C. • *Excess skin removal*–re-operation or

ADVERSE EVENT	MILD	MODERATE	SEVERE
	the skin observed, but no surgical correction needed. • *Injury to penis*–bruising or abrasion, or limited superficial laceration or burn injury not requiring additional dressings.	discernible and additional sutures or skin mobilisation needed for wound closure, but no other intervention needed. • *Injury to penis*–significant laceration or burn injury requiring either prolonged follow-up care and attention or repeated or additional dressings.	referral/transfer to another facility required. • *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, transfer or transfusion; or significant burn injury leading to significant tissue necrosis/loss.
SX: Sexual Complications/Undesirable sensory changes	C-SX: Occasional inability to have erection or dissatisfied with sexual performance, no psycho-behavioural consequences.	C-SX: Post-operative changes consistently that 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	B/C-WD: Wound disruption but not extensive enough to require suturing for wound closure.	B/C-WD: Wound disruption extensive enough to require suturing or other clinical intervention (but not surgery).	B/C-WD: Surgical re-exploration is required, or referral/transfer to another facility or hospitalization is required.
OA: Other AEs, Excess swelling of penis/scrotum including haematoma; difficulty urinating; other	B/C-OA: • *Excess swelling*–mild swelling without signs of ongoing bleeding. • *Difficulty urinating*–partial obstruction that is transient in nature, resolving with loosening of the dressing but without any other treatment. • *Other*–N/A.	B/C-OA: • *Excess swelling*–symptoms/signs that require clinical intervention, but not surgical re-exploration. • *Difficulty urinating*–partial 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 a moderate AE). • *Other*–other adverse events related to surgery that result in disability (as	B/C-OA: • *Excess swelling*–surgical re-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. • *Difficulty urinating*–complete obstruction and/or requires placement of a catheter, referral for treatment or surgery to correct. • *Other*–other AE(s) related to the surgery that result in disability (as evidenced by

ADVERSE EVENT	MILD	MODERATE	SEVERE
		evidenced by loss of work or cancellation of normal activities) lasting for at least 4 days after surgery but not more than 7 days.	loss of work or cancellation of normal activities) lasting for at least 8 days after surgery, or result in hospitalization or referral/transfer to another facility.

VMMC EMERGENCY MEDICAL SUPPLIES, EQUIPMENT, AND MEDICINES

REQUIRED				HIGHLY RECOMMENDED		
1. Stethoscope		9. Three sizes of oropharyngeal airways		17. Glucometer		**Comments:**
2. Sphygmomanometer		10. Two sizes of syringes		18. Glucometer strips		
3. Sodium chloride		11. Two sizes of needles				
4. Tourniquet		12. Bags and masks (e.g., Ambu bag) One child size Two adult sizes				
5. IV infusion tubing		13. Exam gloves				
6. Three sizes of IV catheters		14. Alcohol swabs				
7. Adrenaline (10 ampules of 10 ml)		15. Gauze				
8. Hydrocortisone		16. Tape				